L Number	Hits	Search Text	DB	Time stamp
1	8	caro.in. and nasser.xp.	USPAT	2003/08/22 16:34
2	193	600/485.ccls. and 600/500.ccls.	USPAT	2003/08/22 16:34
3	71	(600/485.ccls. or 600/500.ccls.) and (propagation adj (time or speed or velocity))	USPAT	2003/08/22 16:39
4	1	6045509.pn.	USPAT	2003/08/22 16:36
5	13	((600/485.ccls. or 600/500.ccls.) and (propagation adj (time or speed or velocity))) and recalibrat$	USPAT	2003/08/22 16:44
6	1	6190325.pn.	USPAT	2003/08/22 17:46
7	5	(blood adj pressure) and recalibrat$	EPO; JPO; DERWENT; IBM_TDB	2003/08/22 17:48

US006371921B1

(12) **United States Patent**
Caro et al.

(10) **Patent No.: US 6,371,921 B1**
(45) **Date of Patent: Apr. 16, 2002**

(54) **SYSTEM AND METHOD OF DETERMINING WHETHER TO RECALIBRATE A BLOOD PRESSURE MONITOR**

(75) Inventors: **Richard G. Caro; Mark H. Sher**, both of San Francisco, CA (US)

(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/430,928**

(22) Filed: **Nov. 1, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/026,048, filed on Feb. 19, 1998, now Pat. No. 6,045,509, which is a continuation of application No. 08/556,547, filed on Nov. 22, 1995, now Pat. No. 5,810,734, which is a continuation-in-part of application No. 08/228,213, filed on Apr. 15, 1994, now Pat. No. 5,590,649.

(60) Provisional application No. 60/005,519, filed on Oct. 3, 1995.

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/485**; 600/500

(58) **Field of Search** 400/485, 490, 400/493–6, 500

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,583,941	A	1/1952	Gordon, Jr. et al.	
3,090,377	A	5/1963	Salisbury et al.	128/2.05

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

CA	1133211	1/1995
CA	2187638	2/2000

(List continued on next page.)

OTHER PUBLICATIONS

"Characteristics of Impact and Pulse Wave Propagation in Brachial and Radial Arteries", Milton Landowne vol. 12, Jan. 1958, p. 91–97.

"Dispersion and Attenuation of Small Artificial Pressure Waves in the Canine Aorta", Max Anliker, Ph.D., Michael B. Histand, M.S., and Eric Ogden, MRCS, LRCP, Circulation Research, vol. XXIII, Oct. 1968, p. 539–551.

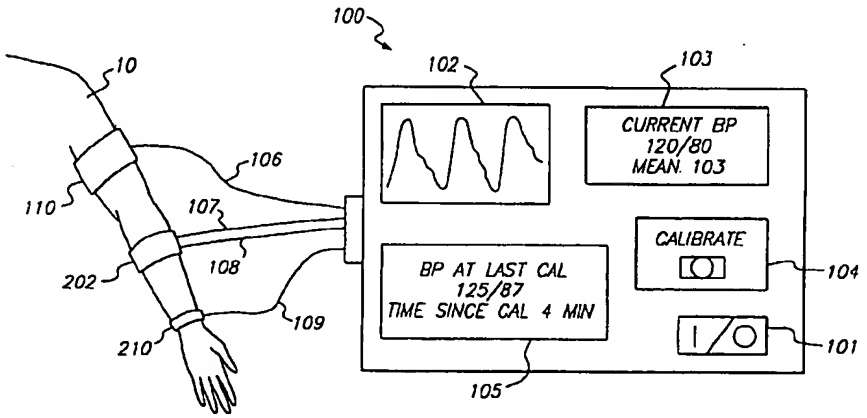
(List continued on next page.)

Primary Examiner—Robert L. Nasser
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

A monitor for determining a patient's physiological parameter includes a calibration device configured to provide a calibration signal representative of the patient's physiological parameter. An exciter is positioned over a blood vessel of the patient for inducing a transmitted exciter waveform into the patient. A noninvasive sensor is positioned over the blood vessel, where the noninvasive sensor is configured to sense a hemoparameter and to generate a noninvasive sensor signal representative of the hemoparameter containing a component of a received exciter waveform. In this context, a hemoparameter is defined as any physiological parameter related to vessel blood such as pressure, flow, volume, velocity, blood vessel wall motion, blood vessel wall position and other related parameters. A processor is configured to determine a relationship between a property of the received exciter waveform and a property of the physiological parameter. The processor is connected to receive the calibration signal and the noninvasive sensor signal, and the processor is configured to process the calibration signal and the noninvasive sensor signal to determine the physiological parameter. In the preferred embodiment, the physiological parameter measured is blood pressure, however, the present invention can also be used to analyze and track other physiological parameters such as vascular wall compliance, strength of ventricular contractions, vascular resistance, fluid volume, cardiac output, myocardial contractility and other related parameters.

9 Claims, 14 Drawing Sheets



U.S. PATENT DOCUMENTS

3,095,872	A	*	7/1963	Tolles 600/485
3,280,817	A		10/1966	Jorgensen et al.
3,318,303	A		5/1967	Hammacher
3,773,033	A		11/1973	Rodbard et al.
3,880,145	A		4/1975	Blick
3,885,551	A		5/1975	Massie
4,074,711	A		2/1978	Link et al.
4,141,350	A		2/1979	Shinoda
4,154,238	A		5/1979	Link
4,172,450	A		10/1979	Rogers et al.
4,181,134	A		1/1980	Mason et al.
4,202,348	A		5/1980	Abe et al.
4,203,451	A		5/1980	Panico
4,250,894	A		2/1981	Frei et al.
4,265,251	A		5/1981	Tickner
4,269,193	A		5/1981	Eckerle
4,295,471	A		10/1981	Kaspari
4,307,728	A		12/1981	Albert
4,343,314	A		8/1982	Sramek
4,349,034	A		9/1982	Ramsey, III
4,406,289	A		9/1983	Wesseling et al.
4,409,983	A		10/1983	Albert
4,423,738	A		1/1984	Newgard
4,443,730	A		4/1984	Kitamura et al.
4,475,554	A		10/1984	Hyndman
4,510,940	A		4/1985	Wesseling
4,524,777	A		6/1985	Kishioka et al.
4,539,997	A		9/1985	Wesseling et al.
4,561,447	A		12/1985	Kawamura et al.
4,562,843	A		1/1986	Djordjevich et al.
RE32,180	E		6/1986	Lewiner et al.
4,646,754	A		3/1987	Seale
4,660,566	A		4/1987	Palti
4,669,152	A		6/1987	Alexander
4,669,485	A		6/1987	Russell
4,718,426	A		1/1988	Russell
4,718,427	A		1/1988	Russell
4,718,428	A		1/1988	Russell
4,771,792	A		9/1988	Seale
4,784,152	A		11/1988	Shinoda et al.
4,791,915	A		12/1988	Barsotti et al.
4,796,184	A		1/1989	Bahr et al.
4,799,491	A		1/1989	Eckerle
4,802,488	A		2/1989	Eckerle
4,846,189	A		7/1989	Sun
4,869,261	A		9/1989	Penaz
4,873,987	A		10/1989	Djordjevich et al.
4,907,596	A		3/1990	Schmid et al.
4,924,871	A		5/1990	Honeyager
4,960,128	A		10/1990	Gordon et al.
5,033,471	A		7/1991	Yokoe et al.
5,099,853	A		3/1992	Uemura et al.
5,101,829	A		4/1992	Fujikawa et al.
5,111,817	A		5/1992	Clark et al. 128/633
5,148,807	A		9/1992	Hsu
5,163,438	A		11/1992	Gordon et al.
5,165,416	A		11/1992	Shinoda et al.
5,237,997	A		8/1993	Greubel et al.
5,241,963	A		9/1993	Shankar
5,241,964	A		9/1993	McQuilkin
5,261,414	A		11/1993	Aung et al.
5,267,565	A		12/1993	Beard
5,279,303	A		1/1994	Kawamura et al.
5,309,916	A		5/1994	Hatschek
5,337,750	A		8/1994	Walloch 600/494
5,339,818	A		8/1994	Baker et al.
5,390,679	A		2/1995	Martin
5,394,877	A		3/1995	Orr et al.
5,423,322	A		6/1995	Clark et al.
5,425,372	A		6/1995	Takeda
5,439,001	A		8/1995	Butterfield et al.
5,447,163	A		9/1995	Apple
5,494,043	A		2/1996	O'Sullivan et al.
5,533,511	A	*	7/1996	Kaspari et al. 600/494
5,551,440	A		9/1996	Miyawaki
5,590,649	A		1/1997	Caro et al.
5,640,964	A		6/1997	Archibald et al.
5,722,414	A		3/1998	Archibald et al.
5,785,659	A		7/1998	Caro et al.
5,791,347	A		8/1998	Flaherty et al.
5,807,268	A		9/1998	Reeves et al.
5,810,734	A		9/1998	Caro et al.
5,830,131	A		11/1998	Caro et al.
5,833,618	A	*	11/1998	Caro et al. 600/485
5,904,654	A		5/1999	Wohltmann et al.
6,027,452	A		2/2000	Flaherty et al.
6,045,509	A		4/2000	Caro et al.
6,190,325	B1	*	2/2001	Narimatsu 600/494

FOREIGN PATENT DOCUMENTS

EP	0 443 267 A1 A1	8/1991
JP	4097738	3/1992
JP	2831471	9/1998
WO	WO86/04801	8/1986
WO	WO90/00029	1/1990
WO	WO 9005482	5/1990
WO	WO 9516391	6/1995
WO	WO 95/28126	10/1995
WO	WO 9712545	5/1997

OTHER PUBLICATIONS

"Measurement of Pulse–Wave Velocity Using a Beat–Sampling Technique", J.D. Pruett, J.D. Bourland, L.A. Geddes, Annals of Biomedical Engineering, vol. 16, p. 341–347, 1988.

"Application Note #3 About Lock–In Amplifiers", Stanford Research Systems, Scientific and Engineering Instruments, 1992–1993, p. 129–139.

"Vibration technique for indirect measurement of diastolic arterial pressure in human fingers", H. Shimazu, H. Ito, A. Kawarada, H. Kobayashi, A. Hiraiwa, K. Yamakoshi, Med. & Biol. Eng. & Comput., Mar. 1989, 27, p. 130–136.

"Continuous Non–Invasive Blood Pressure Measurement Using Arterial Pressure Wave Velocity", R.G. Pearl, L.C. Siegel, T. Nishimura, M.H. Sher, B.T. Flaherty, I. McLoughlin, B.C. Caro, Stanford University School of Medicine, 1995.

R. Cobbold, RF and Microwave Designer's Handbook, pp. 504–510, 766–776 (Note, Applicants are no longer in possession of a copy of this reference. To the best of Applicants knowledge, the reference was submitted during prosecution of U.S. Application No. 08/606,563, now U.S. Patent No. 5,904,654).

G. Gravlee, et al., "Accuracy of four Indirect Methods of Blood Pressure Measurement, With Hemodynamic Correlations," Journal of Clincal Monitoring, vol. 6, No. 4, Oct. 1990, pp. 284–298. (Note, Applicants are no longer in possession of a copy of this reference. To the best of Applicants knowledge, the reference was submitted during the prosecution of U.S. Application No. 08/672,218, now U.S. Patent No. 6,027,452).

"Medwave: A New Choice: Vasotrac™ APM 205 Blood Pressure Monitor," Brochure, Medwave, Inc. 1995. (Note, Applicants are no longer in possession of a copy of this reference. To the best of Applicants knowledge, the reference was submitted during the prosecution of U.S. Application No. 08/672,218, now U.S. Patent No. 6,027,452).

M. Ramsey, III, "Blood Pressure Monitoring: Automated Oscillometric Devices," Journal of Clinical Monitoring, vol. 7, No. 1, Jan. 1991, pp. 56–67. (Note, Applicants are no longer in possession of a copy of this reference. To the best of Applicants knowledge, the reference was submitted during the prosecution of U.S. Application No. 08/672,218, now U.S. Patent No. 6,027,452).

H. Shimazu et al., "Electric Impedance Cuff for the Indirect Measurement of Blood Pressure and Volume Elastic Modulus in Human Limb and Finger Artieres," Medical Biological Engineering & Computing, vol. 27, Sep. 1989, pp. 477–483.

"Transducers for Biomedical Measurements: Principles and Applications," Institute of Biomedical Engineering, pp. 170–173.

PCT International Search Report, App. No.: PCT/US95/12452, App. Date: Nov. 20, 1995, 2 pages.

PCT International Search Report, App. No.: PCT/US96/15820, App. Date: Mar. 26, 1997, 3 pages.

PCT International Search Report, App. No.: PCT/US96/15879, App. Date: Dec. 7, 1996, 2 pages.

PCT International Search Report, App. No.: PCT/US96/15951, App. Date: Mar. 10, 1996, 5 pages.

PCT International Search Report, App. No.: PCT/US96/15956, App. Date: Jan. 7, 1997, 3 pages.

PCT International Search Report, App. No.: PCT/US97/10381, App. Date: Jun. 12, 1997, 3 pages.

PCT International Search Report, App. No.: PCT/US97/13743, App. Date: Oct. 17, 1997, 3 pages.

PCT International Search Report, App. No.: PCT/US00/30250, App. Date: Jan. 11, 2000, 3 pages.

PCT International Search Report, App. No.: PCT/US95/04124, App. Date: Apr. 3, 1995, 3 pages.

* cited by examiner-

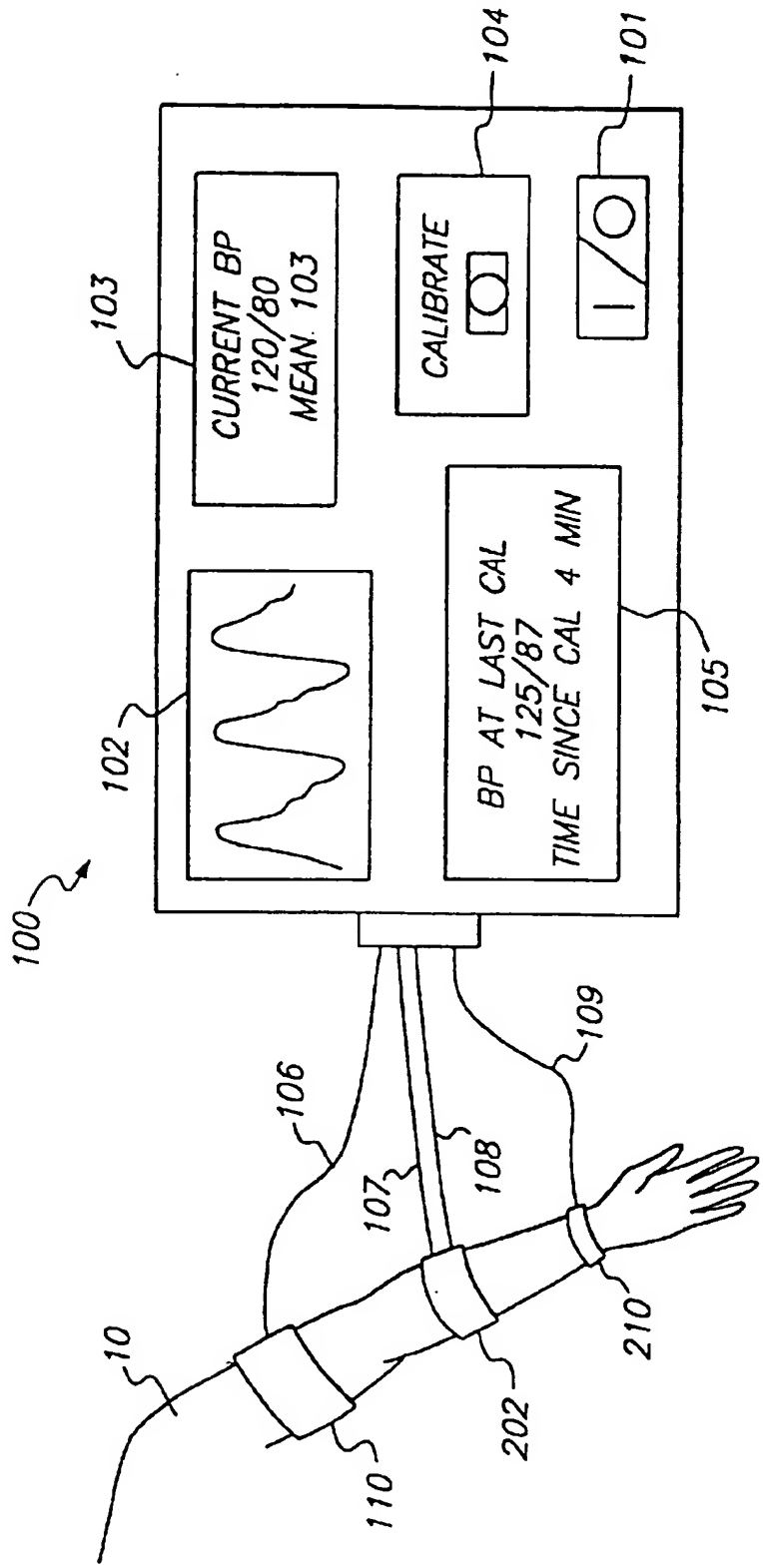

104
101
103
CURRENT BP
120/80
MEAN 103
CALIBRATE
102
BP AT LAST CAL
125/87
TIME SINCE CAL 4 MIN
105
100
109
106
108
107
10
210
202
110

FIG. 1

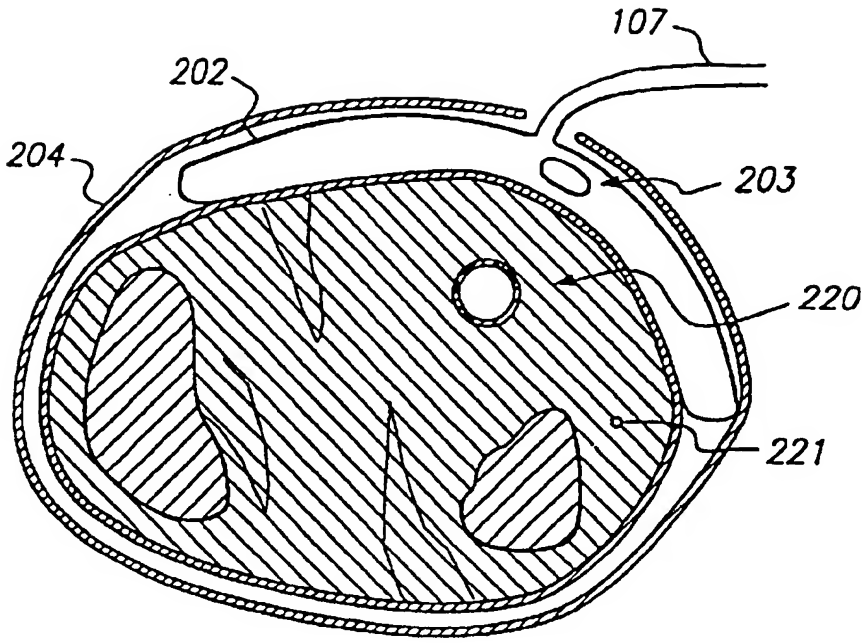


FIG. 2

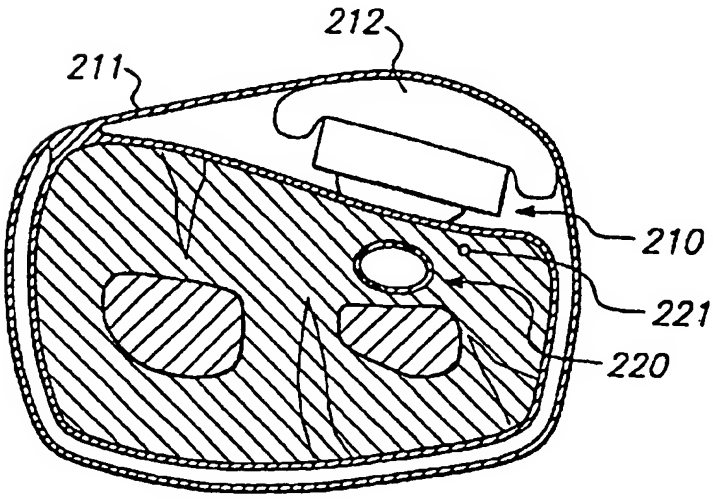


FIG. 3

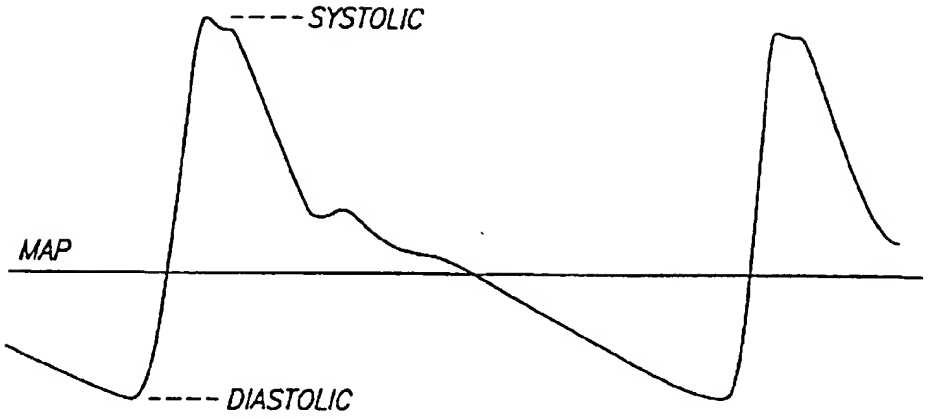


FIG. 4a

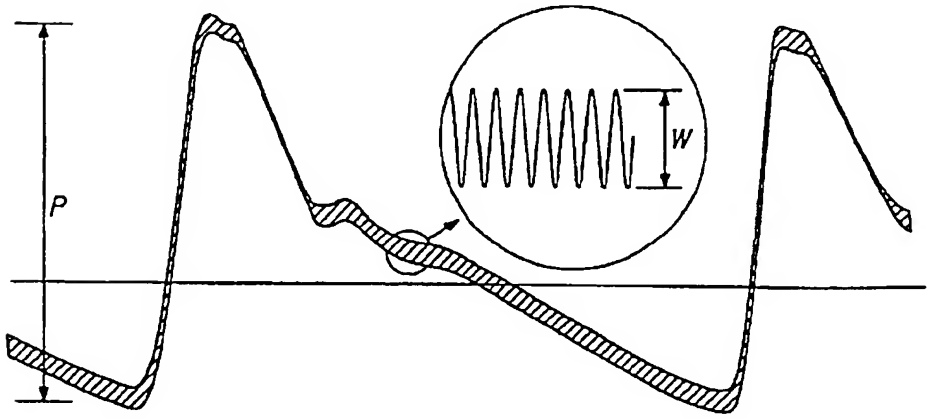
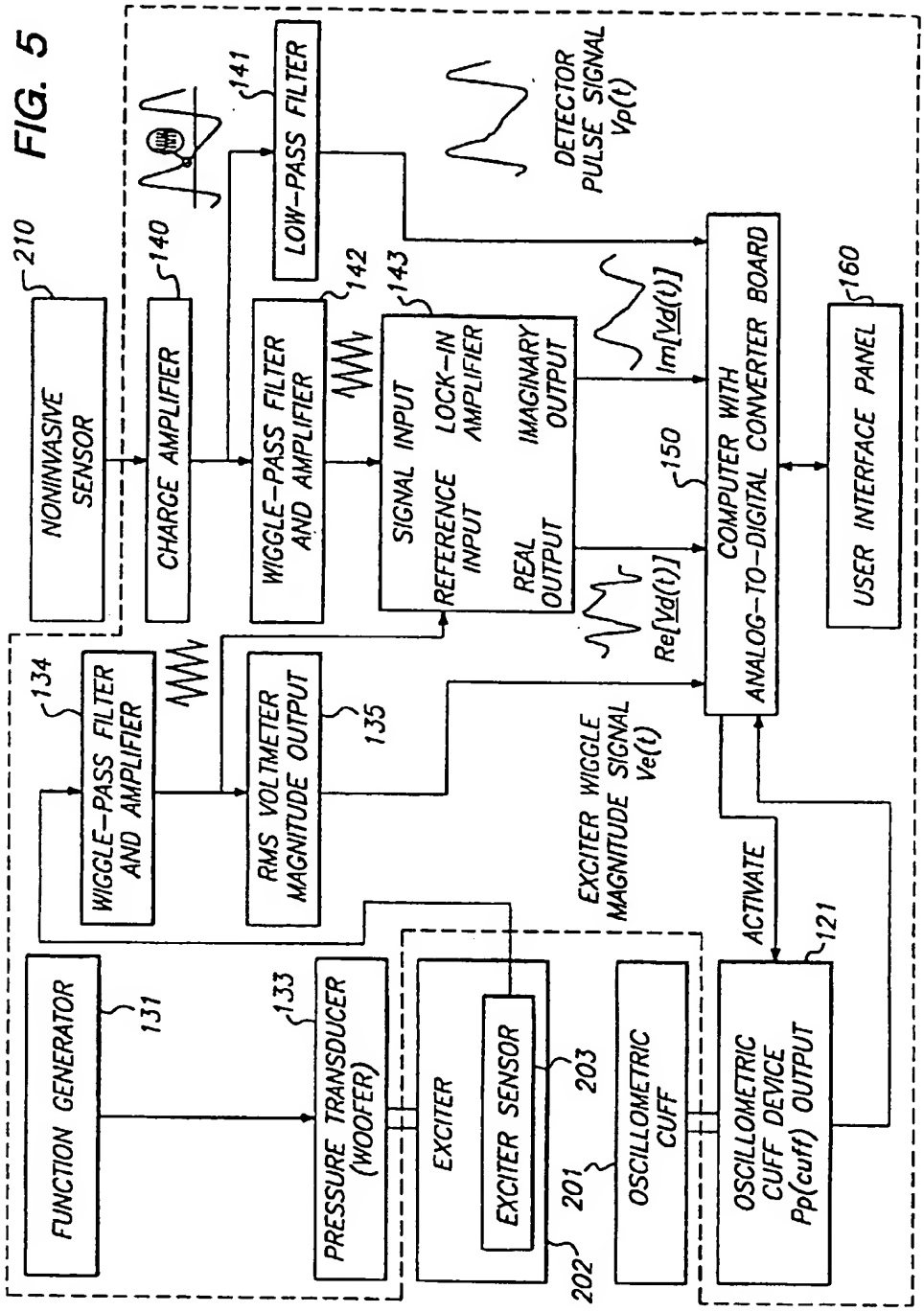


FIG. 4b

FIG. 5


NONINVASIVE SENSOR
210
CHARGE AMPLIFIER
140
LOW-PASS FILTER
141
WIGGLE-PASS FILTER AND AMPLIFIER
142
LOCK-IN AMPLIFIER
143
SIGNAL INPUT
REFERENCE INPUT
IMAGINARY OUTPUT
REAL OUTPUT
DETECTOR PULSE SIGNAL
Vp(t)
Im[Vd(t)]
Re[Vd(t)]
150
COMPUTER WITH ANALOG-TO-DIGITAL CONVERTER BOARD
160
USER INTERFACE PANEL
WIGGLE-PASS FILTER AND AMPLIFIER
134
RMS VOLTMETER MAGNITUDE OUTPUT
135
EXCITER WIGGLE MAGNITUDE SIGNAL
Ve(t)
ACTIVATE
121
FUNCTION GENERATOR
131
PRESSURE TRANSDUCER (WOOFER)
133
EXCITER
EXCITER SENSOR
203
201
202
OSCILLOMETRIC CUFF
OSCILLOMETRIC CUFF DEVICE
Pp(cuff) OUTPUT

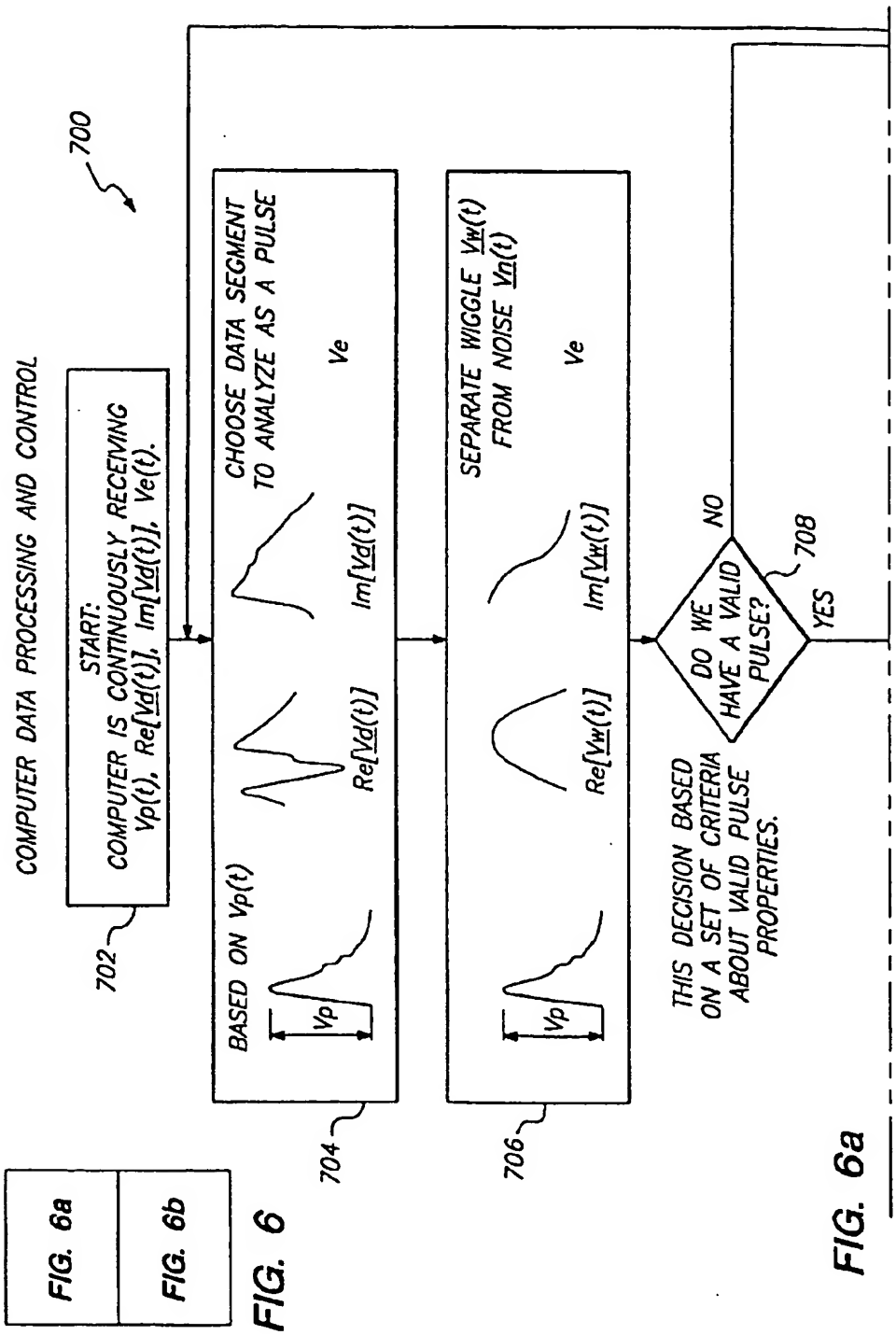


FIG. 6a

FIG. 6

FIG. 6a
FIG. 6b

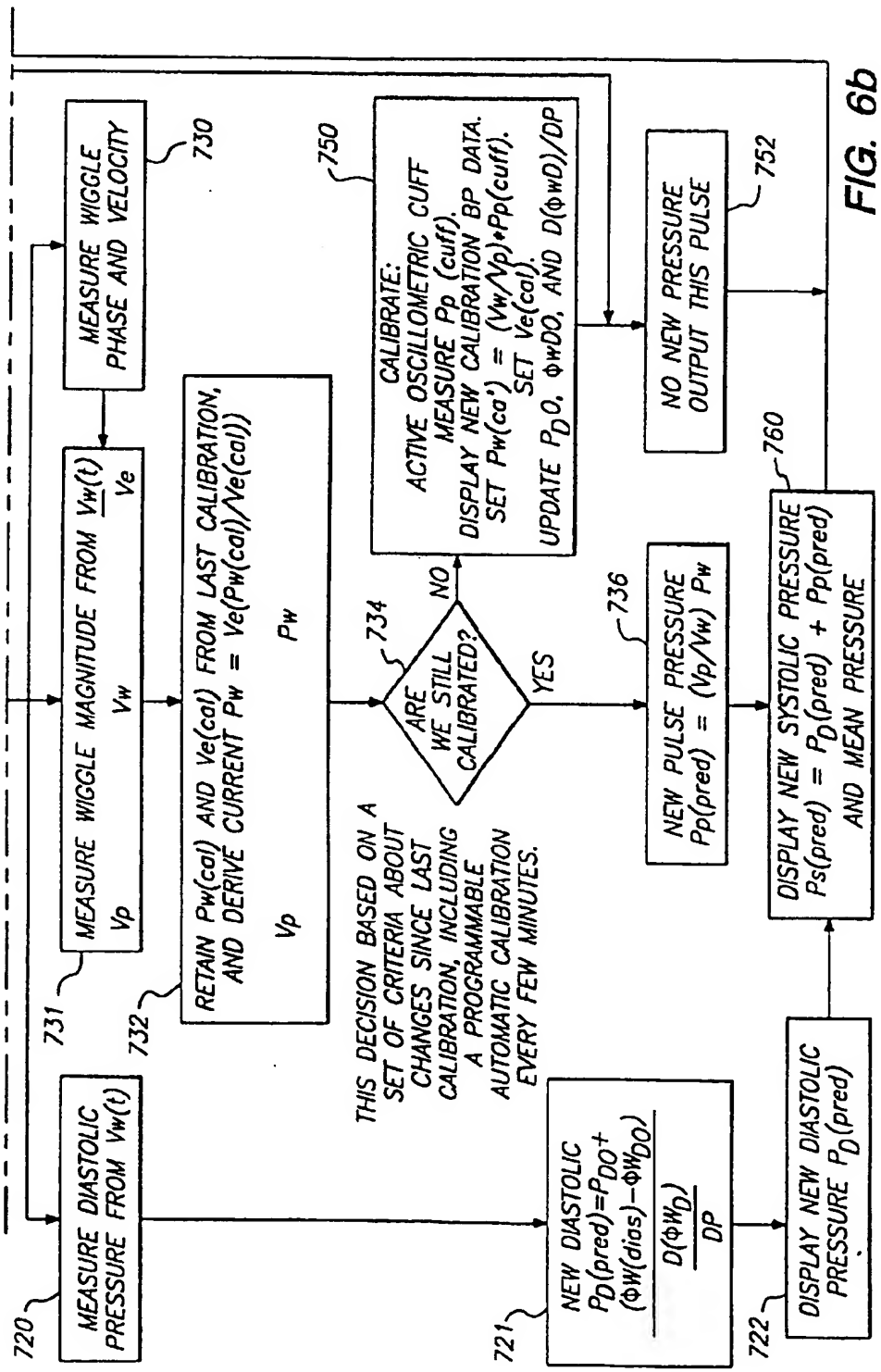

MEASURE DIASTOLIC PRESSURE FROM Vw(t)
720
MEASURE WIGGLE MAGNITUDE FROM Vw(t) Vw Vp Ve
731
MEASURE WIGGLE PHASE AND VELOCITY
730
RETAIN Pw(cal) AND Ve(cal) FROM LAST CALIBRATION, AND DERIVE CURRENT Pw = Ve(Pw(cal)/Ve(cal)) Pw Vp
732
ARE WE STILL CALIBRATED?
734
NO
YES
CALIBRATE: ACTIVE OSCILLOMETRIC CUFF MEASURE Pp (cuff). DISPLAY NEW CALIBRATION BP DATA. SET Pw(ca') = (Vw/Vp)*Pp(cuff). SET Ve(cal). UPDATE PD0, ΦwDO, AND D(ΦwD)/DP
750
NEW PULSE PRESSURE Pp(pred) = (Vp/Vw) Pw
736
NO NEW PRESSURE OUTPUT THIS PULSE
752
DISPLAY NEW SYSTOLIC PRESSURE Ps(pred) = PD(pred) + Pp(pred) AND MEAN PRESSURE
760
THIS DECISION BASED ON A SET OF CRITERIA ABOUT CHANGES SINCE LAST CALIBRATION, INCLUDING A PROGRAMMABLE AUTOMATIC CALIBRATION EVERY FEW MINUTES.
NEW DIASTOLIC PD(pred)=PDO+ (Φw(dias)−ΦwDO) D(ΦwD)/DP
721
DISPLAY NEW DIASTOLIC PRESSURE PD(pred)
722

FIG. 6b

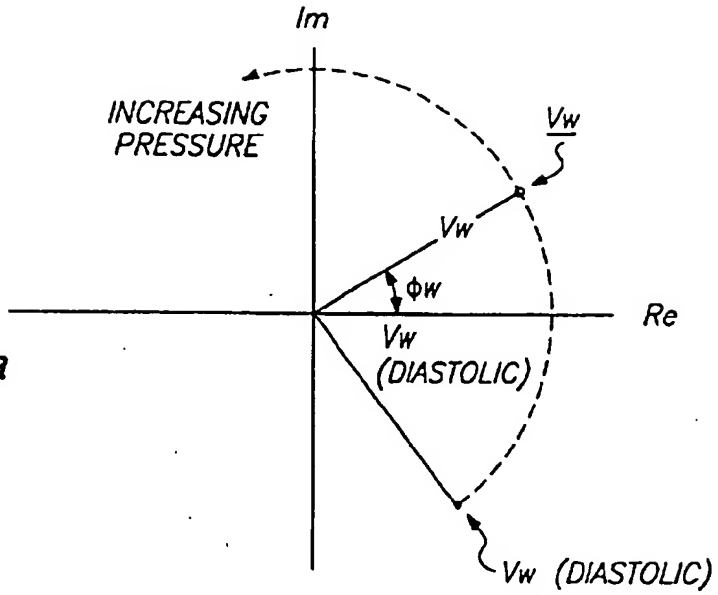


FIG. 7a

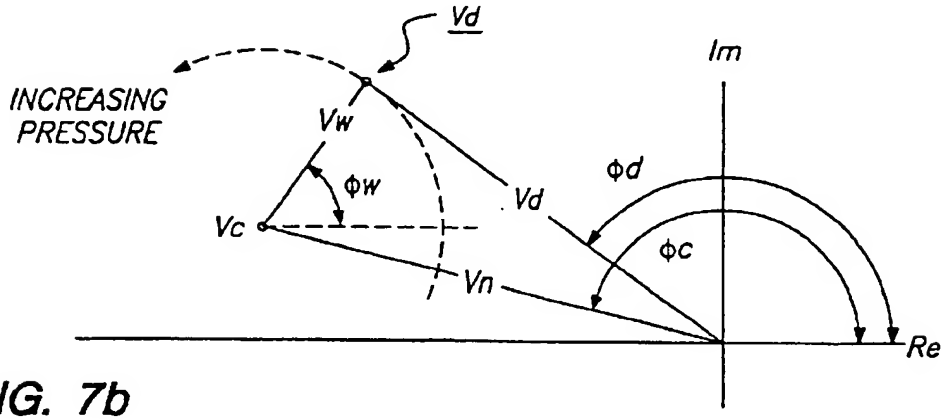


FIG. 7b

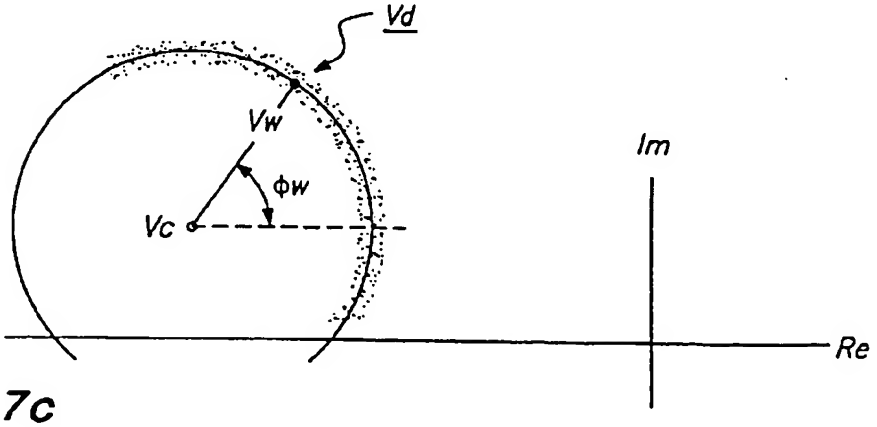


FIG. 7c

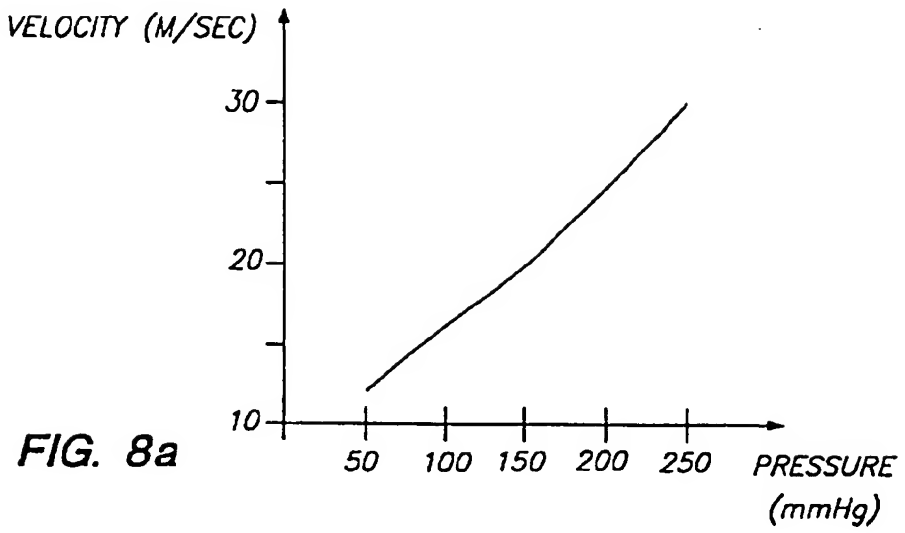


FIG. 8a

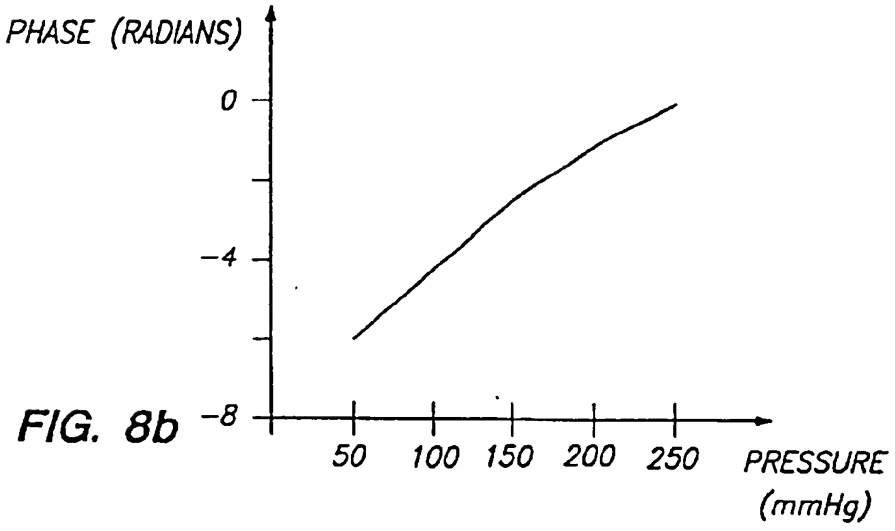


FIG. 8b

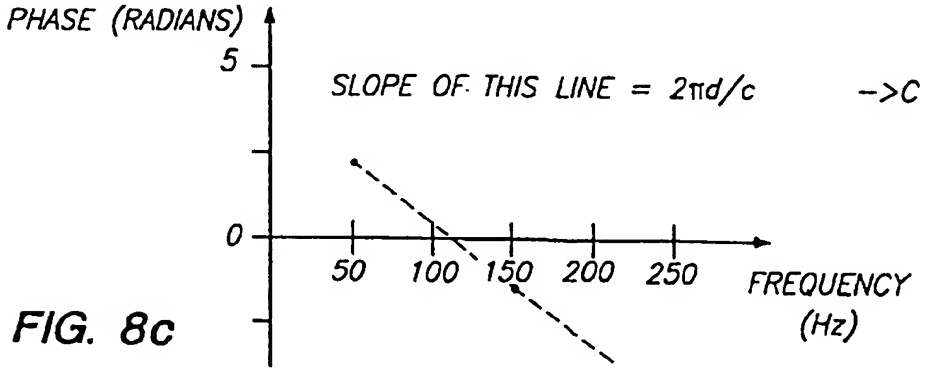
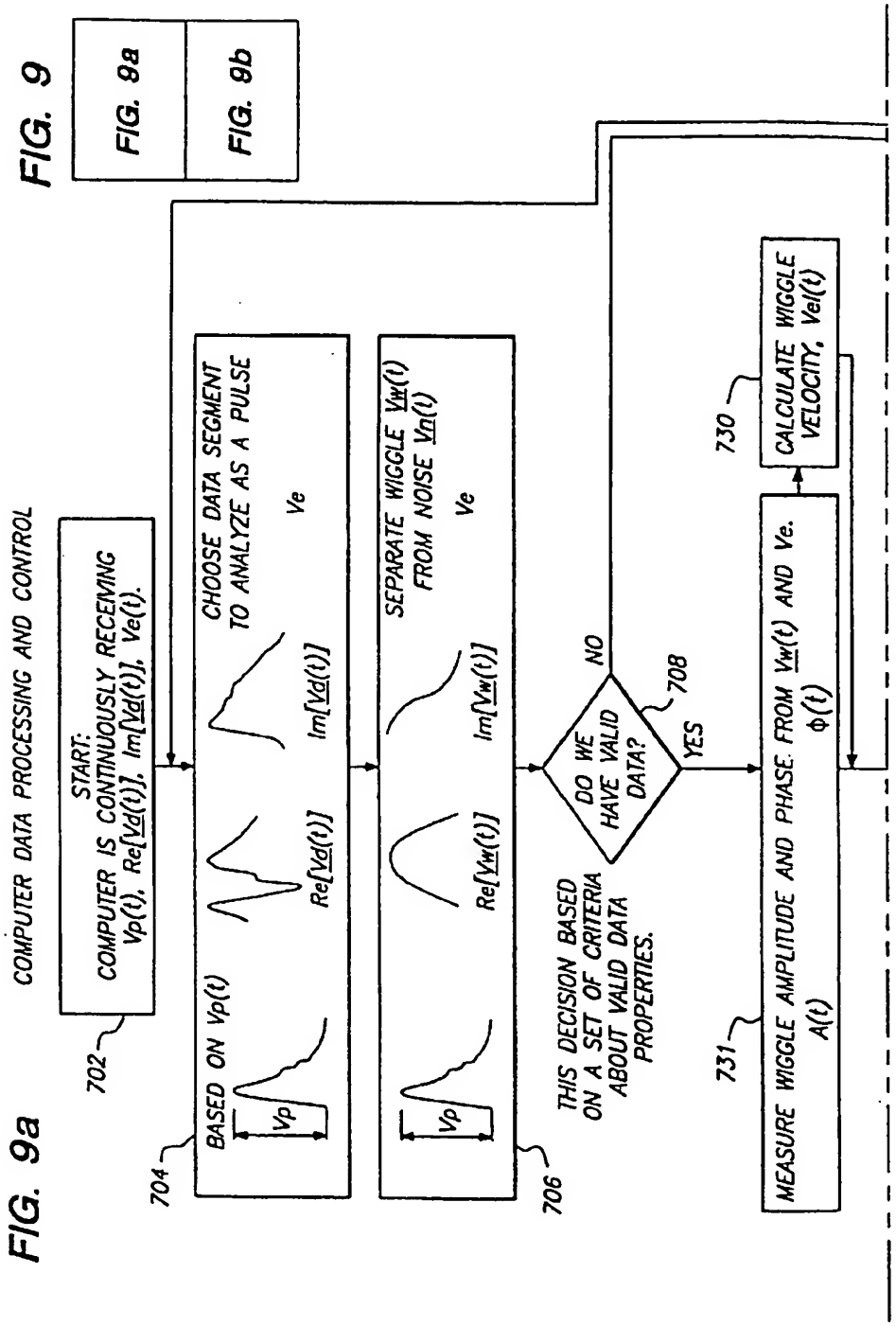


FIG. 8c

FIG. 9

FIG. 9a
FIG. 9b

FIG. 9a


COMPUTER DATA PROCESSING AND CONTROL
START:
COMPUTER IS CONTINUOUSLY RECEIVING
Vp(t), Re[Vd(t)], Im[Vd(t)], Ve(t).
702
BASED ON Vp(t)
Vp
CHOOSE DATA SEGMENT
TO ANALYZE AS A PULSE
Ve
Re[Vd(t)]
Im[Vd(t)]
704
SEPARATE WIGGLE Vw(t)
FROM NOISE Vn(t)
Ve
Re[Vw(t)]
Im[Vw(t)]
706
DO WE
HAVE VALID
DATA?
708
NO
YES
THIS DECISION BASED
ON A SET OF CRITERIA
ABOUT VALID DATA
PROPERTIES.
MEASURE WIGGLE AMPLITUDE AND PHASE FROM Vw(t) AND Ve.
A(t)
φ(t)
731
CALCULATE WIGGLE
VELOCITY, Vel(t)
730

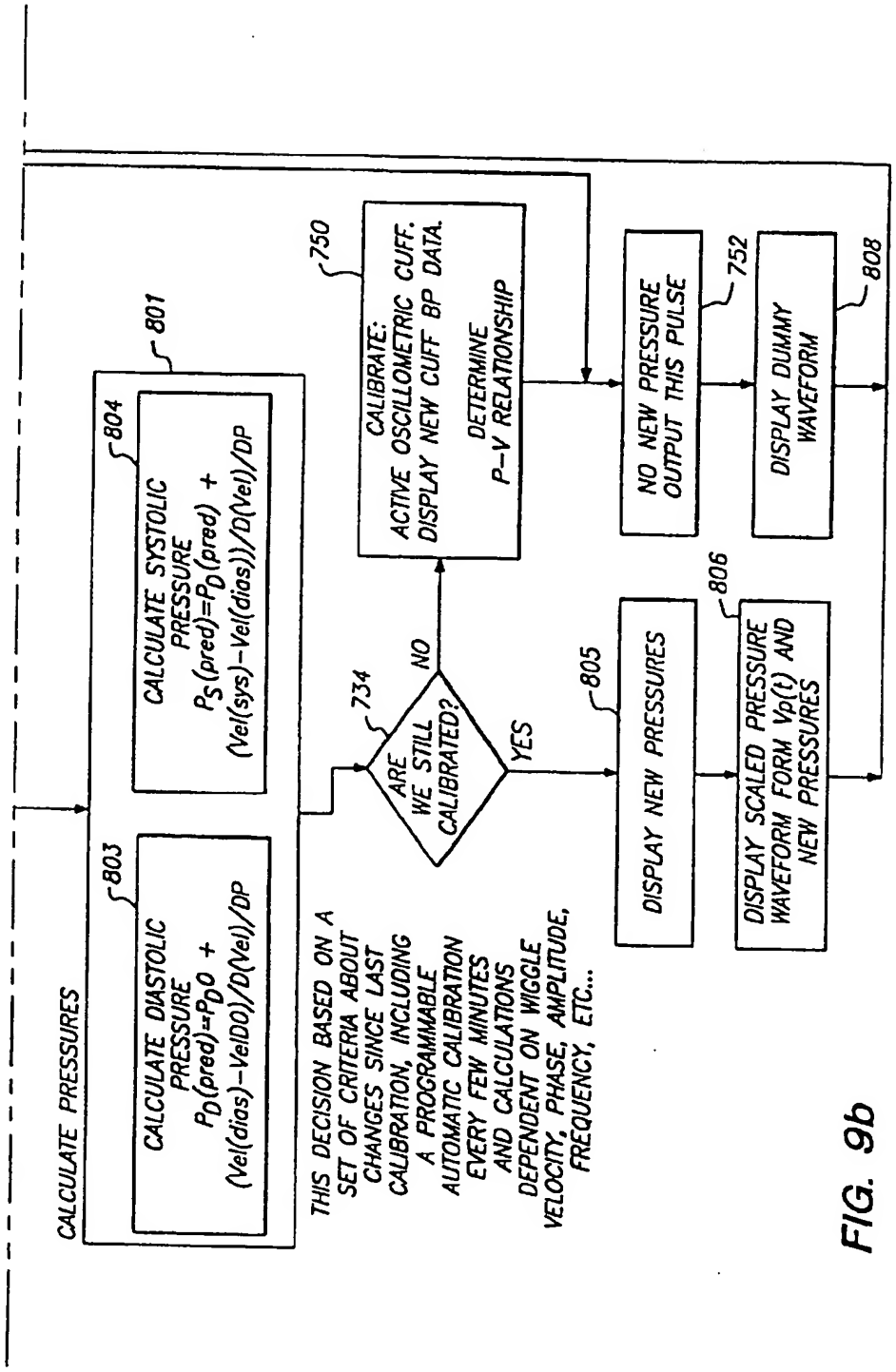

CALCULATE PRESSURES
803
CALCULATE DIASTOLIC PRESSURE
$P_D(pred)=P_D0$ + (Vel(dias)−VelD0)/D(Vel)/DP
804
CALCULATE SYSTOLIC PRESSURE
$P_S(pred)=P_D(pred)$ + (Vel(sys)−Vel(dias))/D(Vel)/DP
801
THIS DECISION BASED ON A SET OF CRITERIA ABOUT CHANGES SINCE LAST CALIBRATION, INCLUDING A PROGRAMMABLE AUTOMATIC CALIBRATION EVERY FEW MINUTES AND CALCULATIONS DEPENDENT ON WIGGLE VELOCITY, PHASE, AMPLITUDE, FREQUENCY, ETC...
734
ARE WE STILL CALIBRATED?
NO
YES
750
CALIBRATE: ACTIVE OSCILLOMETRIC CUFF. DISPLAY NEW CUFF BP DATA.
DETERMINE P–V RELATIONSHIP
805
DISPLAY NEW PRESSURES
806
DISPLAY SCALED PRESSURE WAVEFORM FORM Vp(t) AND NEW PRESSURES
NO NEW PRESSURE OUTPUT THIS PULSE
752
DISPLAY DUMMY WAVEFORM
808

FIG. 9b

FIG. 10

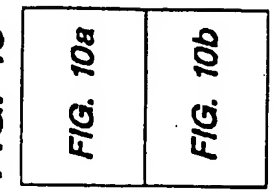
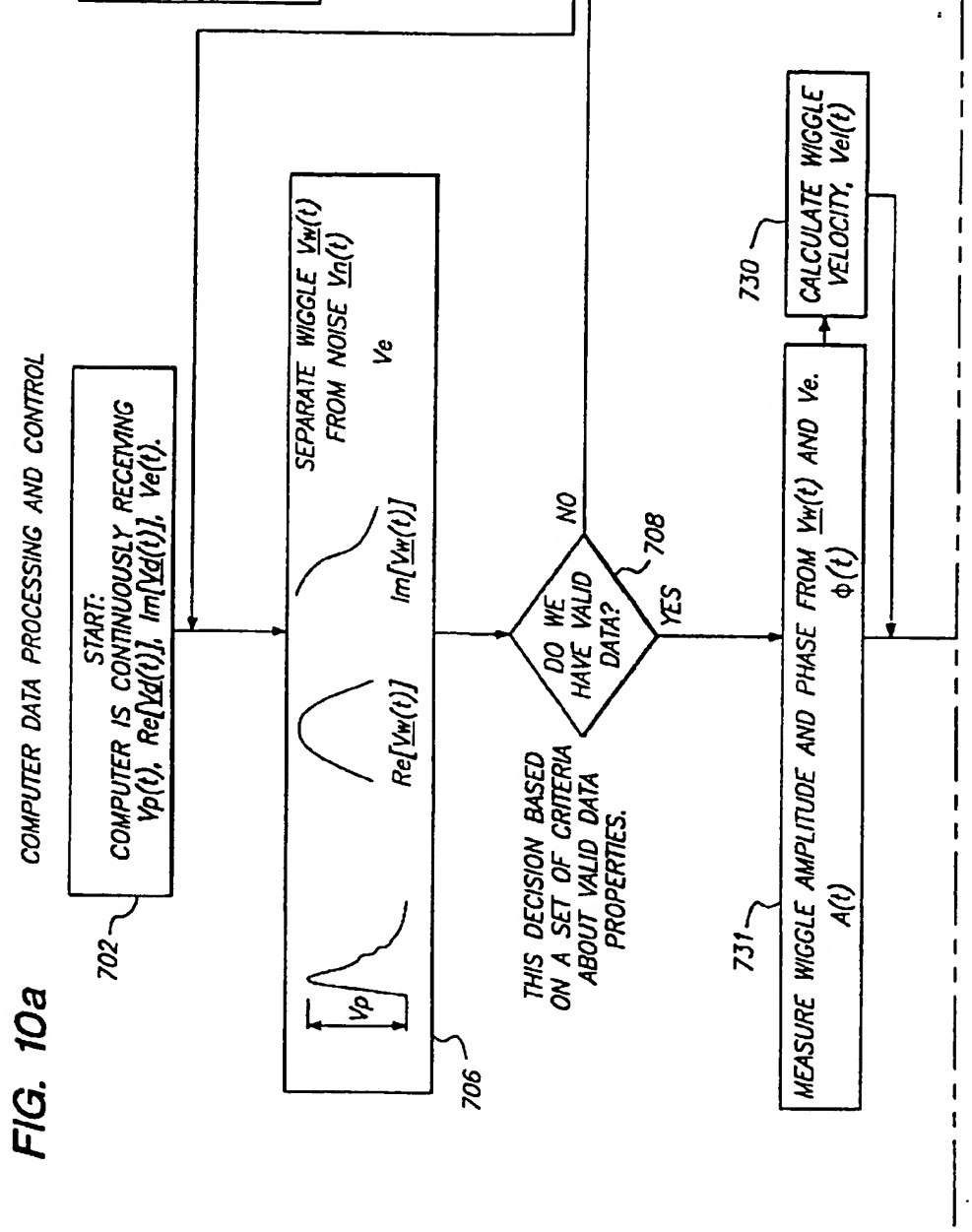


FIG. 10a



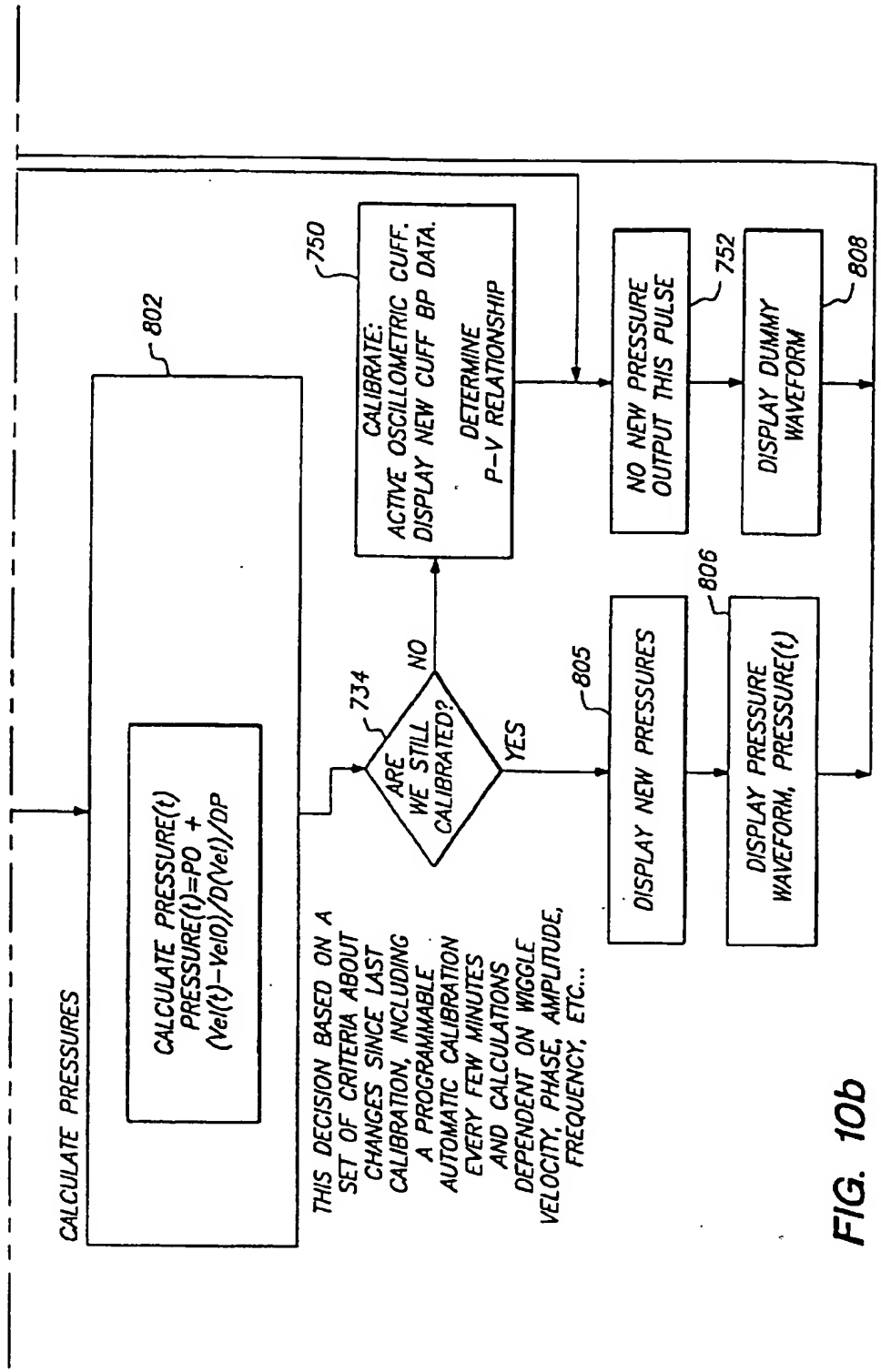

CALCULATE PRESSURES
802
CALCULATE PRESSURE(t)
PRESSURE(t)=P0 +
(Vel(t)-Vel0)/D(Vel)/DP
THIS DECISION BASED ON A SET OF CRITERIA ABOUT CHANGES SINCE LAST CALIBRATION, INCLUDING A PROGRAMMABLE AUTOMATIC CALIBRATION EVERY FEW MINUTES AND CALCULATIONS DEPENDENT ON WIGGLE VELOCITY, PHASE, AMPLITUDE, FREQUENCY, ETC...
734
ARE WE STILL CALIBRATED?
NO
YES
750
CALIBRATE:
ACTIVE OSCILLOMETRIC CUFF.
DISPLAY NEW CUFF BP DATA.
DETERMINE
P-V RELATIONSHIP
805
DISPLAY NEW PRESSURES
806
DISPLAY PRESSURE
WAVEFORM, PRESSURE(t)
NO NEW PRESSURE
OUTPUT THIS PULSE
752
DISPLAY DUMMY
WAVEFORM
808

FIG. 10b

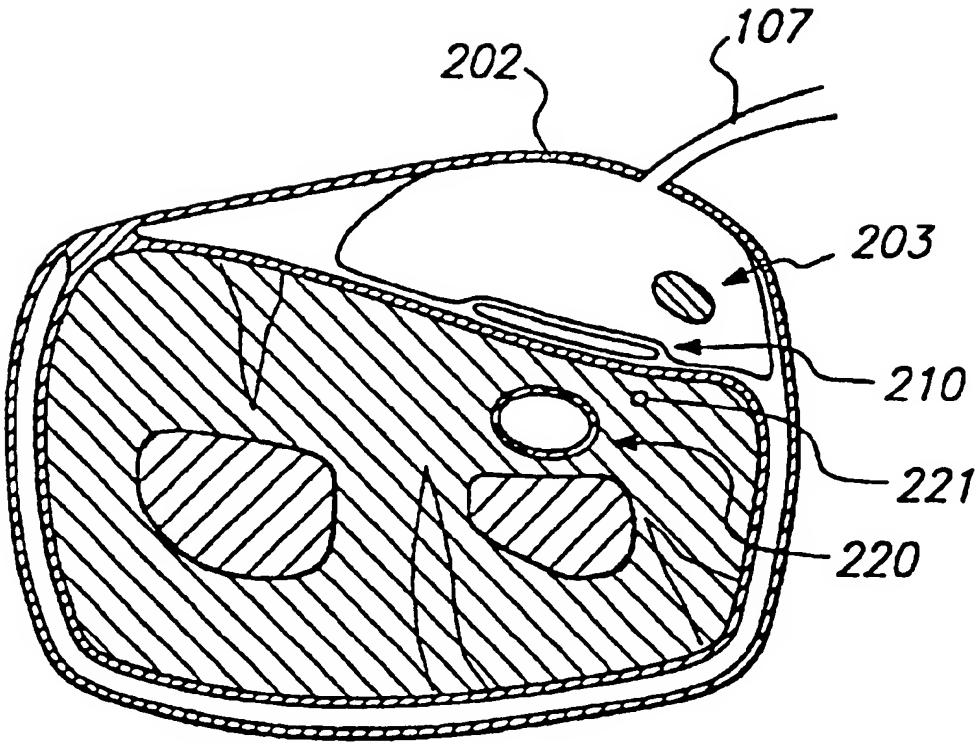


FIG. 11

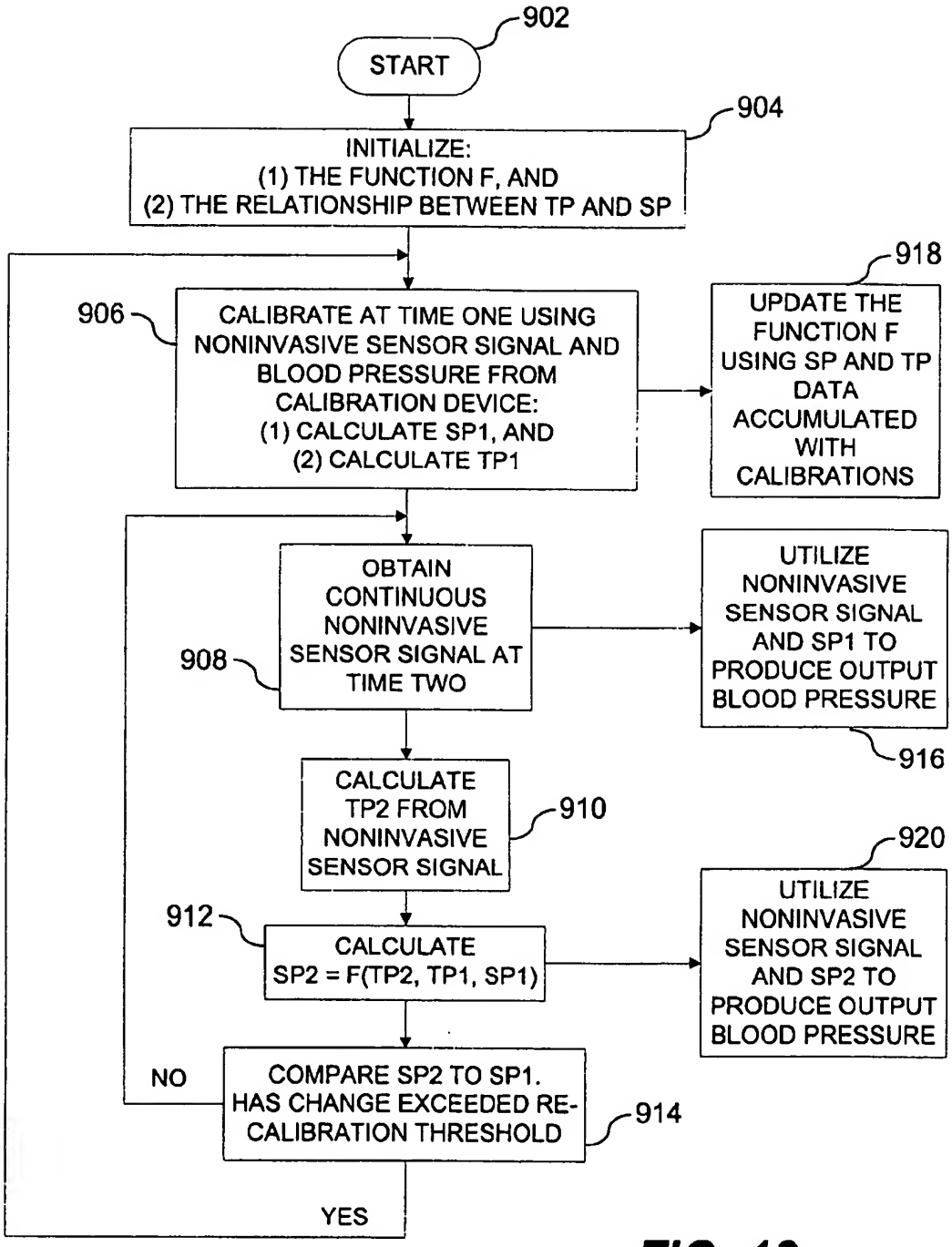

902
START
904
INITIALIZE:
(1) THE FUNCTION F, AND
(2) THE RELATIONSHIP BETWEEN TP AND SP
906
CALIBRATE AT TIME ONE USING NONINVASIVE SENSOR SIGNAL AND BLOOD PRESSURE FROM CALIBRATION DEVICE:
(1) CALCULATE SP1, AND
(2) CALCULATE TP1
918
UPDATE THE FUNCTION F USING SP AND TP DATA ACCUMULATED WITH CALIBRATIONS
908
OBTAIN CONTINUOUS NONINVASIVE SENSOR SIGNAL AT TIME TWO
916
UTILIZE NONINVASIVE SENSOR SIGNAL AND SP1 TO PRODUCE OUTPUT BLOOD PRESSURE
910
CALCULATE TP2 FROM NONINVASIVE SENSOR SIGNAL
912
CALCULATE SP2 = F(TP2, TP1, SP1)
920
UTILIZE NONINVASIVE SENSOR SIGNAL AND SP2 TO PRODUCE OUTPUT BLOOD PRESSURE
NO
914
COMPARE SP2 TO SP1. HAS CHANGE EXCEEDED RE-CALIBRATION THRESHOLD
YES

FIG. 12

SYSTEM AND METHOD OF DETERMINING WHETHER TO RECALIBRATE A BLOOD PRESSURE MONITOR

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 09/026,048, filed Feb. 19, 1998, now U.S. Pat. No. 6,045,509, which is a continuation of U.S. patent application Ser. No. 08/556,547, filed Nov. 22, 1995, now U.S. Pat. No. 5,810,734, which claims priority benefit to U.S. Provisional Application No. 60/005,519, filed Oct. 3, 1995, wherein U.S. Pat. No. 5,810,734 is also a continuation-in-part of U.S. patent application Ser. No. 08/228,213, filed Apr. 15, 1994, now U.S. Pat. No. 5,590,649. U.S. Pat. Nos. 6,045,509, 5,833,618, 5,830,131, and 5,590,649 are incorporated herein by reference.

FIELD

The present invention relates to an apparatus and method for noninvasively providing a determination of a patient's physiological parameter and other clinically important parameters.

BACKGROUND

Blood pressure is the force within the arterial system of an individual that ensures the flow of blood and delivery of oxygen and nutrients to the tissue. Prolonged reduction or loss of pressure severely limits the amount of tissue perfusion and could therefore result in damage to or even death of the tissue. Although some tissues can tolerate hypoperfusion for long periods of time, the brain, heart and kidneys are very sensitive to a reduction in blood flow. Thus, during and after surgery, blood pressure is a frequently monitored vital sign. Blood pressure is affected, during and after surgery, by the type of surgery and physiological factors such as the body's reaction to the surgery. Moreover, blood pressure is manipulated and controlled, during and after surgery, using various medications. Often, these physiological factors and the given medications can result in a situation of rapidly changing blood pressure requiring immediate blood pressure measurement, and corrective action.

Because of changes in the patient's blood pressure, constant monitoring is important. The traditional method of measuring blood pressure is with a stethoscope, occlusive cuff and pressure manometer. However, this technique is slow, subjective in nature, requires the intervention of a skilled clinician and does not provide timely readings frequently required in critical situations.

For these reasons, two methods of measuring blood pressure have been developed: noninvasive, intermittent methods that use an automated cuff device such as an oscillometric cuff; and invasive, continuous (beat-to-beat) measurements that use a catheter.

The oscillometric cuff method typically requires 15 to 45 seconds to obtain a measurement, and should allow sufficient time for venous recovery. Thus, at best there is typically ½ to 1 minute between updated pressure measurements. This is an inordinately long amount of time to wait for an updated pressure reading when fast acting medications are administered. Also, too frequent cuff inflations over extended periods may result in ecchymosis and/or nerve damage in the area underlying the cuff. The invasive method has inherent disadvantages including risk of embolization, infection, bleeding and vessel wall damage.

To address the need for continuous, noninvasive blood pressure measurement, several systems were developed.

One approach relies on blood pressure values in a patient's finger as indicative of the patient's central blood pressure, as in the cases of Penaz, U.S. Pat. No. 4,869,261 and H. Shimazu, Vibration Techniques for Indirect Measurement of Diastolic Arterial Pressure in Human Fingers, Med. and Biol. Eng. and Comp., vol. 27, no. 2, p. 130 (March 1989). Another system uses two cuffs, one on each arm, to determine calibration readings and continuous readings respectively. Another system transforms a time sampled blood pressure waveform into the frequency domain and determines blood pressure based on deviations of the fundamental frequency. Kaspari, et al. U.S. patent application Ser. No. 08/177,448, filed Jan. 5, 1994 provides examples of these systems. An additional class of devices, represented by L. Djordjevich et al. WO 90/00029 (PCT Application), uses electrical conductance to determine blood pressure.

A related area of interest was explored by perturbing the body tissue of patients. One class of experiments causes perturbations by inducing kinetic energy into the patient, specifically, by oscillating a blood vessel. In the work of Seale, U.S. Pat. No. 4,646,754, an attempt is described to measure blood pressure by sensing the input impedance of a blood vessel exposed to a low frequency vibration. In work by H. Hsu, U.S. Pat. No. 5,148,807, vibrations are used in a non-contact optical tonometer. Several experiments measured the velocity of excited perturbations in the blood and demonstrated a correlation between perturbation velocity and blood pressure. Such a correlation has also been demonstrated between pressure and the velocity of the natural pulse wave. However, while these studies discuss the relationship between velocity and pressure they do not propose a practical method of measuring induced perturbations to determine blood pressure. Examples of such studies are M. Landowne, Characteristics of Impact and Pulse Wave Propagation in Brachial and Radial Arteries, J. Appl. Physiol., vol. 12, p. 91 (1958); J. Pruett, Measurement of Pulse-Wave Velocity Using a Beat-Sampling Technique, Annals of Biomedical Engineering, vol. 16, p. 341 (1988); and M. Anliker, Dispersion and Attenuation of Small Artificial Pressure Waves in the Canine Aorta, Circulation Research, vol. 23, p.539 (October 1968).

Known techniques for measuring propagation of pressure perturbations in arteries include Tolles, U.S. Pat. No. 3,095,872 and Salisbury, U.S. Pat. No. 3,090,377. Tolles employs two sensors to detect a perturbation waveform and generate two sensor signals. The two sensor signals are compared in a phase detector. The phase difference of the sensor signals is displayed giving a signal that is capable of detecting changes in blood pressure, but which does not provide a calibrated blood pressure output. Salisbury similarly employs a sensor to detect a perturbation waveform and generate a single sensor signal. The sensor signal is compared against a reference signal. Based on the phase difference of the sensor signal, a universal formula is employed to determine the patient's blood pressure. Since it has been shown, for example by Landowne, that the relationship between pressure and signal propagation varies considerably from patient to patient, Salisbury's technique, based on a single formula, is not generally applicable.

OBJECTS AND SUMMARY OF THE INVENTION

The present invention describes an apparatus and method for measuring the induced perturbation of a patient's body tissue to determine the patient's blood pressure and other clinically important parameters.

An object of the present invention is to continuously determine a patient's blood pressure via a noninvasive sensor attached to the patient.

A related object is to induce a perturbation into a patient's blood or blood vessel and to noninvasively measure the perturbation to determine the patient's blood pressure.

A related object is to filter the noninvasive sensor signal into components including a natural component, an induced component and a noise component, and to determine the patient's blood pressure from the induced component.

A further related object is to determine a relationship between a property of an induced perturbation and a property of a physiological parameter.

A monitor for determining a patient's physiological parameter includes a calibration device configured to provide a calibration signal representative of the patient's physiological parameter. An exciter is positioned over a blood vessel of the patient for inducing a transmitted exciter waveform into the patient. A noninvasive sensor is positioned over the blood vessel, where the noninvasive sensor is configured to sense a hemoparameter and to generate a noninvasive sensor signal representative of the hemoparameter containing a component of a received exciter waveform. In this context, a hemoparameter is defined as any physiological parameter related to vessel blood such as pressure, flow, volume, velocity, blood vessel wall motion, blood vessel wall position and other related parameters. A processor is configured to determine a relationship between a property of the received exciter waveform and a property of the physiological parameter. The processor is connected to receive the calibration signal and the noninvasive sensor signal, and the processor is configured to process the calibration signal and the noninvasive sensor signal to determine the physiological parameter. In the preferred embodiment, the physiological parameter measured is blood pressure, however, the present invention can also be used to analyze and track other physiological parameters such as vascular wall compliance, strength of ventricular contractions, vascular resistance, fluid volume, cardiac output, myocardial contractility and other related parameters.

BRIEF DESCRIPTION OF THE FIGURES

Additional advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings, in which:

FIG. **1** depicts the present invention attached to a patient;

FIG. **2** depicts an exciter attached to a patient;

FIG. **3** depicts a noninvasive sensor attached to a patient;

FIG. **4***a* depicts a blood pressure waveform;

FIG. **4***b* depicts a blood pressure waveform with an exciter waveform superimposed thereon;

FIG. **5** depicts a schematic diagram of the present invention;

FIGS. **6***a–b* depict a processing flow chart according to one embodiment of the invention;

FIGS. **7***a–c* are graphical illustrations of the filter procedures of the present invention;

FIGS. **8***a–c* are graphical illustrations showing the relationships between the exciter waveform and blood pressure;

FIGS. **9***a–b* depict a processing flow chart according to another embodiment of the invention;

FIGS. **10***a–b* depict a processing flow chart according to another embodiment of the invention;

FIG. **11** depicts an exciter and noninvasive sensor attached to a patient; and

FIG. **12** is a flowchart showing the operation of Internal Consistency Analysis according to an embodiment of the invention.

GLOSSARY

GLOSSARY

P_D	diastolic blood pressure
P_{Do}	diastolic blood pressure at calibration
P_s	systolic blood pressure
P_p	pulse pressure
P_w	exciter waveform pressure
V_d	received exciter waveform
V_w	signal exciter waveform
V_n	noise waveform
V_e	exciter sensor signal (transmitted exciter waveform)
V_p	detected pulsatile voltage
ΦW	exciter signal phase
ΦW_D	exciter signal phase at diastole
Vel(t)	exciter signal velocity
Vel_D	exciter signal velocity at diastole
Vel_s	exciter signal velocity at systole

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment concentrates on the physiological parameter of blood pressure, however, many additional physiological parameters can be measured with the present invention including vascular wall compliance, ventricular contractions, vascular resistance, fluid volume, cardiac output, myocardial contractility and other related parameters. Those skilled in the art will appreciate that various changes and modifications can be made to the preferred embodiment while remaining within the scope of the present invention. As used herein, the term continuous means that the physiological parameter of interest is determined over a period of time, such as during the course of surgery. The implementation of portions of the invention in a digital computer is performed by sampling various input signals and performing the described procedures on a set of samples. Hence, a periodic determination of the physiological parameter of interest is within the definition of the term continuous.

FIG. **1** illustrates the components and configuration of the preferred embodiment. Oscillometric cuff **110** is connected to processor **100** via wire **106**, and cuff **110** is responsive to processor **100** during an initial calibration step. Oscillometric cuff operation, which is known in the art, involves an automated procedure for obtaining a blood pressure signal. The general procedure is given for clarity but is not crucial to the invention.

First, an occlusive cuff is pressurized around the patient's upper arm to abate the blood flow. Then, as the pressure is slowly reduced, a transducer senses when the blood flow begins and this pressure is recorded as the systolic pressure. As the pressure is further reduced, the transducer similarly detects the pressure when full blood flow is restored and this pressure is recorded as the diastolic pressure. The signals representing pressure are delivered, via wire **106**, to processor **100** for storage. An alternative blood pressure measurement technique such as manual or automated sphygmomanometry using Korotkoff sounds or "return to flow" techniques, could also be used. A manual measurement can be provided, for example, using a keypad. Whatever measurement technique is used, a calibration device provides a calibration signal representative of the patient's physiological parameter. In this respect, the calibration device is broadly defined to include automated or manual measurements.

FIG. **1** shows an exciter **202** attached to the patient's forearm above the radial artery. The exciter **202** is a device

for inducing a perturbation of the patient's body tissue, and is controlled by the processor **100** via tube **107**.

FIG. **2** shows a cross section of the exciter and its components. The exciter **202** is an inflatable bag attached to the processor via air tube **107**. It is fixed in place near an accessible artery **220** by holddown device **204** which can be a buckle, adhesive strap or other device. There is also an exciter sensor **203** disposed within the exciter to generate a reference signal indicative of the perturbation source waveform, and to deliver the signal to the processor via wire **108**. This signal is used as a reference signal by the processor (explained below). In certain cases, the exciter drive voltage or current can be used as the reference signal and the exciter sensor **203** is a simple current or voltage sensor. In such a case, a signal representative of the exciter current or voltage is delivered to the processor via wire **108**. The exciter sensor may also be contained within the processor and connected to the exciter by an electrical connection such as a wire.

As mentioned above, processor **100** is attached to the exciter via tube **107**. The processor **100** controls the pressure in exciter **202** with a transducer and diaphragm. A transducer is a device that transforms an electrical signal to physical movement, and a diaphragm is a flexible material attached to the transducer for amplifying the movement. An example of this combination is a loudspeaker. The diaphragm forms part of an airtight enclosure connected to air tube **107** and an input to initialize the pressure. It will be clear to one skilled in the art that the transducer and air tube **107** and exciter **202** can be miniaturized and combined into a single exciter element capable of acting as a vibrating air filled bag connected to the processor by an electrical drive signal alone, in the case that a source of substantially constant pressure such as a spring is included in the exciter, or by an electrical drive signal and connection to a source of substantially constant pressure for the bag. It will be clear to one skilled in the art that the exciter may equally well be coupled to the arm through a fluid medium such as air, or by a solid medium such as a gel.

In operation, the pressure is initially established via the initialization input and then the pressure is varied by an electrical signal delivered to the transducer; the diaphragm produces pressure variations in the tube in response to the transducer movement. The result is that the processor, by delivering an oscillating electrical signal to the transducer, causes oscillating exciter pressure. The exciter responds by perturbing the patient's tissue and inducing a transmitted exciter waveform into the patient. This transmitted exciter waveform should be considered to be a vibrational exciter waveform since it involves a vibrational perturbation of the tissue.

The perturbation excites the tissue **221** and blood vessel **220** below the exciter and causes the transmitted exciter waveform to radiate within the patient's body, at least a portion of which travels along the blood filled vessel. The excitation waveform can be sinusoidal, square, triangular, or of any suitable shape. Experiments conducted to determine a range of satisfactory perturbation frequencies found that the range of 20–1000 Hz works well. It is anticipated that frequencies of lesser than 20 Hz and greater than 1000 Hz will also work well, and it is intended that this specification cover all frequencies insofar as the present invention is novel.

FIG. **1** further shows a noninvasive sensor **210** placed at a distance from the exciter on the patient's wrist. The noninvasive sensor is connected to the processor **100** via wire **109**.

FIG. **3** shows a cut-away view of the noninvasive sensor **210** placed over the same radial artery **220** as the exciter. The sensor **210** is fixed in place near the artery **220** by holddown device **211** which can be a buckle, adhesive strap or other device. The holddown device **211** also includes a baffle **212** to reduce noise, where the baffle is a pneumatic bag pressurized to hold the sensor **210** at a constant pressure against the patient, for example at a pressure of 10 mm Hg. Alternately, baffle **212** can be any suitable device such as a spring or foam pad.

The noninvasive sensor **210** is responsive to at least one hemoparameter of the patient and generates a signal in response thereto. In this context, a hemoparameter is defined as any physiological parameter related to vessel blood such as pressure, flow, volume, velocity, blood vessel wall motion, blood vessel wall position and other related parameters. In the preferred embodiment a piezoelectric sensor is used to sense arterial wall displacement, which is directly influenced by blood pressure. It will be clear to one skilled in the art that a microphone or other sensor could be used as the noninvasive sensor. The sensor may be connected to the arm by a fluid or solid coupling such as an air filled cavity or a gel.

As is shown, the sensor is positioned over the radial artery **220** and it is responsive to pressure variations therein; as the pressure increases, the piezoelectric material deforms and generates a signal corresponding to the deformation. The signal is delivered to the processor **100** via wire **109**.

FIG. **1** also shows the processor **100** that has a control panel for communicating information with the user. A power switch **101** is for turning the unit on. A waveform output monitor **102** displays the continuous blood pressure waveform for medical personnel to see. This waveform is scaled to the pressures determined by the processor, and output to the monitor. A digital display **103** informs the user of the current blood pressure; there is a systolic over diastolic and mean pressure shown. A calibrate button **104** permits the user to calibrate the processor at any time, by pressing the button. The calibration display **105** shows the user the blood pressure at the most recent calibration, and also the elapsed time since calibration. The processor maintains a record of all transactions that occur during patient monitoring including calibration blood pressure, calibration times, continuous blood pressure and other parameters, and it is anticipated that additional information can be stored by the processor and displayed on the control panel.

Turning to the noninvasive sensor signal, in addition to a natural hemoparameter, the noninvasive sensor signal contains a component indicative of the exciter waveform traveling through the patient. Although the exciter component is designed to be small in comparison to the natural hemoparameter, it contains valuable information. Therefore, the processor is used to separate the exciter waveform from the natural hemoparameter, and to quantify the respective components to determine the patient's blood pressure.

FIG. *4a* shows a natural blood pressure waveform where the minimum represents the diastolic pressure and the maximum represents the systolic pressure. This waveform has a mean arterial pressure (MAP) that is a convenient reference for purposes of determining the DC offset of the waveform. Example pressure values are 80 mm Hg diastolic and 120 mm Hg systolic respectively with a MAP DC offset of 90 mmHg.

FIG. *4b* shows an operational illustration of the arterial waveform; an exciter waveform superimposed on a natural blood pressure waveform. The exciter induces the exciter

waveform into the arterial blood at a first location and the exciter waveform becomes superimposed on the natural waveform. Since the exciter waveform is small compared to the patient's natural waveform, the natural waveform dominates as shown in FIG. 4*b*. As mentioned above, the noninvasive sensor signal contains information regarding both the natural waveform and the exciter waveform. The processor **100** is designed to separate the constituent components of the noninvasive sensor signal to continuously determine the patient's blood pressure, as is discussed below.

FIG. **5** depicts a schematic diagram of the preferred embodiment. There is an oscillometric cuff controller **121** for controlling the oscillometric cuff and determining the readings therefrom to generate a signal representing the patient's blood pressure. There is an induced wave frequency generator **131** coupled to a pressure transducer **133** that transforms an electrical input to a pressure output. The transducer output is connected to the exciter **202** and controls the exciter's oscillations for inducing the exciter waveform into the patient's arterial blood.

The output of the exciter sensor **203** is fed to a band pass filter **134**. This filter **134** separates the high frequency signal responsive to the transducer pressure and delivers the resulting signal to RMS meter **135** and to lock-in amplifier **143** reference input. In the preferred embodiment, the RMS meter output is sampled at a rate of 200 samples per second with a 14 bit resolution and delivered to computer **150**. It is anticipated that the sampling rate and resolution can be varied with good results.

The output of the noninvasive sensor is fed to a charge amplifier **140** that delivers a resulting signal to a low pass filter **141** and a band pass filter **142**. These filters separate the noninvasive sensor signal into two constituent components representing an uncalibrated natural blood pressure wave and a received exciter waveform respectively. The low pass filter output is sampled at a rate of 200 samples per second with 14 bit resolution and delivered to computer **150**, and the band pass filter output is delivered to the lock-in amplifier **143** signal input.

The lock-in amplifier **143** receives inputs from band pass filter **134** as reference and band pass filter **142** as signal, which are the exciter sensor signal (transmitted exciter waveform) and noninvasive sensor exciter signal (received exciter waveform) respectively. The lock-in amplifier uses a technique known as phase sensitive detection to single out the component of the noninvasive sensor exciter signal at a specific reference frequency and phase, which is that of the exciter sensor signal. The amplifier **143** produces an internal, constant-amplitude sine wave that is the same frequency as the reference input and locked in phase with the reference input. This sine wave is then multiplied by the noninvasive sensor exciter signal and low-pass filtered to yield a signal proportional to the amplitude of the noninvasive sensor signal multiplied by the cosine of the phase difference between the noninvasive exciter signal and the reference. This is known as the in-phase or real output.

The amplifier **143** also produces an internal reference sine wave that is 90 degrees out-of-phase with the reference input. This sine wave is multiplied by the received exciter signal and low-pass filtered to yield a signal proportional to the amplitude of the noninvasive sensor signal multiplied by the sine of the phase difference between the noninvasive sensor exciter signal and the reference. This is known as quadrature or imaginary output. The amplifier **143** then provides the computer **150** with information regarding the real and imaginary components of the received exciter signal as referenced to the phase of the transmitted exciter signal. Alternately, the amplifier can provide components representing the magnitude and phase of the received exciter signal. In the preferred embodiment, the amplifier output is sampled at a rate of 200 samples per second with a 14 bit resolution. It is anticipated that the sampling rate and resolution can be varied with good results.

The computer **150** receives input from the oscillometric cuff controller **121**, RMS meter **135**, low pass filter **141** and lock-in amplifier **150**. The computer **150** also receives input from the user interface panel **160** and is responsible for updating control panel display information. The computer **150** executes procedures for further separating constituent components from the noninvasive sensor signal and attenuating the noninvasive sensor noise component as shown in FIG. **6**.

While the processing system described in the embodiments involves the use of a lock-in amplifier **143**, it will be clear to those persons skilled in the art that similar results can be achieved by frequency domain processing. For example, a Fourier transform can be performed on the various signals to be analyzed, and processing in the frequency domain can be further performed that is analogous to the described processing by the lock-in amplifier in the time domain. The various filtering steps described above can be advantageously performed in the frequency domain. Processing steps in the frequency domain are considered as falling within the general category of the analysis of the transfer function between the exciter sensor waveform and the noninvasive sensor waveform and are intended to be covered by the claims. The variety of techniques that are used in the art for the calculation of transfer functions are also applicable to this analysis.

A. Process Exciter Waveform Velocity to Determine Offset Scaling and Exciter Waveform Amplitude to Determine Gain Scaling

FIG. **6** is a processing flowchart that represents the operation of the FIG. **5** computer **150**. The operation begins at step **702** with the receipt of an initial calibration measurement; noninvasive sensor signal and exciter sensor signal. Step **704** chooses the blood pressure waveform segment for pulse reference, which is important for continuity of measurement from pulse to pulse and for consistency over periods of time between calibration measurements. In this embodiment, the diastolic pressure (low-point) is chosen for purposes of simplicity, but any point of the waveform can be chosen such as the systolic pressure or mean arterial pressure (MAP). The choice of the segment will relate to the DC offset discussed below.

Step **706** is a filter step where the noninvasive sensor (received) exciter waveform is separated into signal and noise components. The noise components may have many sources, one of which is a signal derived from the exciter that travels to the noninvasive sensor by an alternate path, other than that along the artery taken by the signal of interest. Examples include bones conducting the exciter waveform and the surface tissue such as the skin conducting the exciter waveform. Additional sources of noise result from patient movement. Examples include voluntary patient motion as well as involuntary motion such as movement of the patient's limbs by a physician during surgery.

FIGS. 7*a–c* illustrate the principles of the received exciter signal filtering. During a natural pulse, the received exciter waveform V_d is represented by a collection of points that are generated in the complex plane by the real and imaginary outputs of the lock-in amplifier **143** which is monitoring the

noninvasive sensor signal. FIG. 7*a* represents the received exciter waveform V_d in the absence of noise. In the absence of noise, V_d is the same as vector $V_w(t)$ which has a magnitude and phase corresponding to the received exciter signal. During a pulse, the magnitude of $V_w(t)$ remains constant, but the angle periodically oscillates from a first angle representing a lesser pressure to a second angle representing a greater pressure. Note that in the absence of noise, the arc has a center at the origin.

FIG. 7*b* represents the received exciter waveform V_d in the presence of noise, which is indicated by vector V_n. Vector V_d has a magnitude and phase according to the noninvasive sensor exciter waveform plus noise. As can be seen in FIGS. 7*b–c*, vector $V_d(t)$ defines a collection of points forming an arc having a common point V_c equidistant from each of the collection of points. The vector $V_w(t)$ from V_c to the arc corresponds to the true magnitude and phase of the noninvasive signal exciter waveform. The vector V_n represents noise and, once identified, can be removed from the noninvasive sensor waveform. The filter step removes the V_n, noise component and passes the $V_w(t)$ signal exciter component on to step **708**.

In the above discussion, it was assumed for illustrative purposes that the magnitude of $V_w(t)$ remains constant over the time of a pulse. In some cases the attenuation of the exciter waveform as it propagates along the artery is pressure dependent, and in those cases the magnitude of $V_w(t)$ can vary during the pulse in a way that is correlated to pressure. Under such circumstances the shape of the figure traced out in the complex plane by the vector V_d will deviate from a perfect circle segment. A typical shape is that of a spiral with a form that can be predicted theoretically. The functioning of this filter step under such circumstances is conceptually similar to that described above, except that the elimination of the noise vector V_n must involve location of the origin of a spiral rather than of the center of a circle.

Step **708** determines if the pulse is valid. To do this, the processor checks the constituent components of the noninvasive sensor signal to insure that the components are within acceptable clinical norms of the patient. For example, the processor can determine whether the new pulse is similar to the prior pulse, and if so, the new pulse is valid.

Step **720** processes the signal exciter waveform $V_w(t)$ to determine the DC offset. For convenience the diastole is used as the offset value, but any part of the waveform can be used. The processor determines the offset when the vector $V_w(t)$ reaches its lowest phase angle (i.e., the maximum clockwise angle of FIG. 7*a*); this is the diastole phase angle $\Phi w(dias)$. A calibration diastolic measurement is stored by the processor at calibration as P_{D0}. Also stored by the processor is a relationship denoting the relationship between the velocity of an exciter wave and blood pressure. This relationship is determined by reference to a sample of patients and is continuously updated by reference to the particular patient after each calibration measurement. FIGS. 8*a–c* are graphical illustrations showing clinically determined relationships between the exciter waveform and blood pressure. FIG. 8*b* represents the relationship between phase and pressure at a frequency of 150 Hz; other frequencies have relationships that are vertically offset from the line shown. The pressure-velocity relationship represents the storage of this graphical information either in a data table or by an analytical equation.

Step **721** determines the predicted diastolic pressure from the information in Step **720**. The processor continuously determines the change in diastole from one pulse to the next by referencing the position of the signal exciter vector $V_w(t)$, at $\Phi w(dias)$, with respect to the stored pressure-velocity relationship. Moreover, the pressure-velocity relationship is continuously updated based on calibration measurement information gained from past calibrations of the patient.

A set of established relationships is used to develop and interpret information in the table and to relate the information to the sensor signal components. First, a known relationship exists between blood pressure and exciter waveform velocity. Also, at a given frequency many other relationships are known: a relationship exists between velocity and wavelength, the greater the velocity the longer the wavelength; and a relationship exists between wavelength and phase, a change in wavelength will result in a proportional change in phase. Hence, a relationship exists between blood pressure and phase, and a change in blood pressure will result in a proportional change in phase. This is the basis for the offset prediction.

With the stored calibration measurement plus the change in diastole, the new DC offset diastolic pressure is predicted P_D pred). This prediction is made based on the diastolic pressure at calibration P_{D0} plus the quotient of the phase difference between calibration Φw_{D0} and the present time $\Phi w(dias)$ and the pressure-velocity relationship stored in processor memory as rate of change of exciter waveform phase to pressure $d(\Phi w_D)/dP$.

$$P_D(pred) = P_{D0} + \frac{(\Phi w(dias) - \Phi w_{D0})}{d(\Phi w_D)/dP} \quad (1)$$

Step **722** displays the predicted diastolic pressure.

Step **730** determines the noninvasive sensor exciter waveform phase and velocity. This determination is made based on the comparison of the noninvasive sensor exciter waveform with the exciter sensor waveform.

Step **731** determines the noninvasive sensor exciter waveform amplitude from the noninvasive sensor signal.

Step **732** determines the exciter waveform pressure P_w by multiplying the exciter sensor waveform magnitude V_e by the ratio of the calibrated exciter waveform pressure $P_w(cal)$ to the calibrated exciter sensor waveform magnitude $V_e(cal)$.

$$P_w = V_e * \frac{P_w(cal)}{V_e(cal)} \quad (2)$$

In situations where a significant pressure variation can be observed in the attenuation of the exciter waveform as it propagates from exciter to detector, an additional multiplicative pressure dependent correction factor must be included in equation 1.

Step **734** determines if the calibration values are still valid. This determination can be based on many factors including the time since the last calibration, that the linearity of the pressure-velocity relationship is outside of a reliable range, determination by medical personnel that a new calibration is desired or other factors. As an example of these factors, the preferred embodiment provides user settable calibration times of 2, 5, 15, 30, 60 and 120 minutes, and could easily provide more. Moreover, the curve upon which the pressure is determined is piecewise linear with some degree of overall nonlinearity. If the processor **100** determines that the data is unreliable because the linear region is exceeded, the processor will initiate a calibration step. In one embodiment, an "Internal Consistency" trigger technique is employed to determine the validity of the data and to selectively trigger recalibration. This is called Internal

Consistency Analysis and is described under that heading below. Finally, the calibration can be initiated manually if the operator desires a calibration step. A button **104** is provided on the processor **100** for initiating such calibration manually.

Step **736** predicts a new pulse pressure P_p(pred) by multiplying the exciter waveform pressure P_w by the ratio of the detected pulsatile voltage V_p to the detected exciter waveform magnitude V_w.

$$P_p(pred) = P_w * \left(\frac{V_p}{V_w}\right) \quad (3)$$

This prediction uses the noninvasive sensor exciter waveform to determine the pressure difference between the diastole and systole of the natural blood pressure waveform. For example, if a noninvasive sensor exciter magnitude V_w of 0.3 V relates to a pressure variation P_w of 1 mm Hg and the noninvasive sensor waveform V_p varies from −6 V to +6 V, then the noninvasive sensor waveform represents a pulse pressure excursion P_p(pred) of 40 mm Hg.

Step **760** predicts a new systolic pressure P(pred) by adding the predicted diastolic P_D(pred) and pulse pressures P_p(pred).

$$P_S(pred) = P_D(pred) + P_P(pred) \quad (4)$$

In the above example if the diastole P_D(pred) is 80 mm Hg (DC offset) and the pulse P_p(pred) represents a difference of 40 mm Hg then the new systolic P_S(pred) is 120 mm Hg. Then the new systolic pressure is displayed.

For display purposes the values determined for P_S(pred) and P_D(pred) can be displayed numerically. Similarly, the output waveform for display **102** can be displayed by scaling the noninvasive sensor natural blood pressure waveform prior to output using gain and offset scaling factors so that the output waveform has amplitude, P_p(pred), and DC offset, P_D(pred), equal to those predicted in the above process. The scaled output waveform signal can also be output to other instruments such as monitors, computers, processors and displays to be used for display, analysis or computational input.

Step **750** is taken when step **734** determines that the prior calibration is no longer reliable as described above. A calibration step activates the oscillometric cuff **201** and determines the patient's blood pressure, as described above. The processor **100** uses the calibration measurements to store updated pressure and waveform information relating to the DC offset, blood pressure waveform and exciter waveform. The updated variables include calibration pulse pressure P_p(cal), calibration exciter sensor waveform magnitude V_w(cal), diastolic pressure P_{D0}, diastolic exciter waveform phase Φw_{D0}, the rate of change of exciter waveform phase to pressure $d(\Phi w_D)/dP$ and calibration exciter waveform pressure P_w(cal).

$$P_w(cal) = P_p(cal) * \left(\frac{V_w}{V_p}\right) \quad (5)$$

B. Process Exciter Waveform Velocity to Determine Offset Scaling and Gain Scaling

FIGS. **9***a–b* represent a modification to the previous embodiment. The initial processing steps **702, 704, 706, 708, 730** and **731** represented in the flow chart of FIG. **9** are substantially similar to those described in the previous embodiment depicted in FIG. **6**. In step **730**, exciter waveform velocity Vel(t) and the actual phase delay of the exciter waveform $\Phi(t)$ are related by the equation:

$$\Phi(t) = \Phi_0 - 2\pi d f \mathrm{Vel}(t) \quad (6)$$

where frequency f and distance d between exciter and noninvasive sensor are known. The constant Φ_0 is determined in advance either analytically or empirically, and is dependent on the details of the geometry of the apparatus.

Measurement of $\Phi(t)$ is generally made modulo 2π, and so the measured phase $\Phi_m(t)$ is related to actual phase delay by the equation:

$$\Phi_m(t) = \Phi(t) + 2n\pi \quad (7)$$

where n is an integer also known as the cycle-number, typically in the range of 0–10. While correct deduction of propagation velocity requires a correct choice of n, a correct prediction of pressure using a pressure-velocity relation does not, so long as the same value of n is used in determining $\Phi(t)$ and in determining the pressure-velocity relationship. In such a case, velocity should be considered as a pseudo-velocity rather than an actual measure of exciter waveform propagation speed.

In step **730**, therefore, use of the $\Phi(t)$ equations allows determination of the velocity, or pseudo-velocity, Vel(t) as a function of time. In step **801**, the values of velocity at the systolic and diastolic points of the cardiac cycle are determined as Vel_S and Vel_D. These correspond to the points of minimum and maximum phase delay or to the points of maximum and minimum amplitude of the naturally occurring blood pressure wave detected by the noninvasive sensor. Use of the pressure-velocity relationship stored in the processor is then made to transform the values of velocity at systolic and diastolic points in time to values of pressure. In step **803** the diastolic pressure is determined using the equation:

$$P_D(pred) = P_{D0} + (\mathrm{Vel}_D - \mathrm{Vel}_{D0})/(d\mathrm{Vel}/dP) \quad (8)$$

Step **804** is performed to determine the predicted systolic pressure according to the relationship:

$$P_S(pred) = P_D(Pred) + (\mathrm{Vel}_S - \mathrm{Vel}_D)/(d\mathrm{Vel}/dP) \quad (9)$$

In this illustration the values of P_S and P_D are used to determine the pressure waveform. Similarly, other pairs of values, such as mean pressure and pulse pressure can also be used, and appropriate permutations of the predicted pressure equations are anticipated by this description.

In step **805** the calculated pressures are displayed as numbers, with a typical display comprising display of mean, systolic and diastolic values of the pressure waveform in digital form, together with the observed pulse rate. The values of P_D(pred) and P_S(pred) are used to determine appropriate gain and DC offset scaling parameters by which the naturally occurring blood pressure waveform detected by the noninvasive sensor is scaled prior to output in step **806** as a time varying waveform, shown as **102** in FIG. **1**.

As in the embodiment depicted in FIG. **6**, step **750** involves a calibration step initiated when step **734** determines that the prior calibration is no longer reliable. During the performance of step **750** the pressure-velocity relationship is determined and stored in the processor in the form of a table or of an analytical relationship. During this process, it may be desirable to stop the output portion of the process as shown in step **752** and display a different signal, such as a blank screen, a dashed line display, a blinking display, a square wave, or some other distinguishable signal of calibration such as an audible tone. This step is represented as step **808** in FIG. **9**.

C. Process Exciter Waveform Velocity to Determine Output Blood Pressure Waveform

In both of the previous two embodiments, values of gain Pp(pred) and offset P_D(pred) are determined and used to scale the noninvasive sensor natural blood pressure waveform to provide a time varying output waveform representative of the patient's blood pressure. In this embodiment, the natural blood pressure waveform monitored by the noninvasive sensor is not used in the determination of the output blood pressure waveform. As in the previous embodiment, use is made of the relationship between velocity of the exciter waveform and the blood pressure of the patient to determine the blood pressure. Rather than making such a pressure determination only at the diastolic and systolic points of the cardiac cycle, exciter waveform velocity is measured many times during a cardiac cycle (typically 50–200 times per second) and the resultant determinations of pressure are used to construct the output time varying blood pressure waveform. This process is described below with reference to FIG. **10**.

In this embodiment, the natural blood pressure waveform is not scaled and the noninvasive sensor need not have significant sensitivity to the naturally occurring physiological parameter waveform . Therefore, there is no need to separate the data into pulse segments as in step **704** of FIG. **6**. This feature greatly simplifies the computational task. An additional advantage of this technique is that all of the information used in the analysis process is encoded in the exciter waveform, which is typically at a high frequency compared with that of both the natural blood pressure waveform and that of any artifact signals introduced by patient motion or respiration. Since all of these lower frequency signals can be removed by electronic filtering, this technique is extremely immune to motion induced artifact and similar sources of interference that might otherwise introduce errors into the measurement.

With the exception of this step, the initial processing steps **702**, **706**, **731** and **730** are substantially similar to those of previously described embodiments. The amplitude and phase of the exciter waveform determined in step **731** are continuous functions of time. The exciter waveform phase is converted to exciter waveform velocity as described previously, which is also a continuous function of time.

Using a relationship between pressure and velocity, determined during or subsequent to the initial calibration and periodically redetermined, the time dependent velocity function Vel(t) is readily transformed to a time dependent pressure function P(t). This transformation is represented by step **802**. In a typical case, the pressure-velocity relationship might be as follows:

$$Vel(t)=a+bP(t) \tag{10}$$

where the constants a and b were determined during step **750**. In that case the velocity equation (10) can be used to perform the transformation of step **802**.

Following a variety of checking steps, described below, that ensure the transformation used in **802** was correct, the minimum and maximum points of P(t) are determined for each cardiac cycle and displayed as P_D(pred) and P_S(pred) in step **805**. Then, in step **806**, the entire time dependent waveform is displayed as waveform **102**.

D. Determination of the Pressure-velocity Relationship

In each of the embodiments described thus far, an important step involves the conversion of a measured phase to a deduced exciter waveform velocity, and conversion of that value to a pressure. In the case of the flow chart of FIG. **6**, this process is integral to the calculation of the DC offset pressure P_{DO}. In the case of the embodiment described in FIG. **9**, this process is integral to determination of P_S and P_D. In the case of the embodiment described in FIG. **10**, the process is integral to the determination of pressure at each point in time for which an output value is to be displayed as part of a "continuous" pressure waveform display.

The relationship between pressure and velocity is dependent on many factors including the elastic properties of the artery along which the exciter waveform travels. This relationship varies considerably between patients, and must therefore be determined on a patient by patient basis, although a starting relationship derived from a pool of patients can be used. This determination occurs during step **750** in each of the embodiments described in FIGS. **6**, **9**, and **10**, and the relationship is stored in the processor in either a tabular form, or as an analytical relationship. In step **734** in FIGS. **6**, **9** and **10**, a variety of parameters are examined to determine whether the system calibration continues to be acceptable. As part of that process, it is determined whether the existing pressure-velocity relationship continues to be valid. If not, a recalibration can be initiated. Such a determination can be performed using techniques described earlier or those using multiple perturbations described below. One aspect of the multiple perturbation determination is presented under the heading Internal Consistency Analysis.

E. Multiple Perturbations

For each of the different embodiments described hereto, an additional embodiment is described using multiple perturbation waveforms. All the features and advantages of the prior embodiments are applicable to these embodiments.

In the case of each of the previously described embodiments an embodiment is described in which the apparatus further induces a second exciter waveform into the arterial blood. An example second exciter waveform is one that has a frequency different from that of the first exciter waveform. It is noted that although the discussion of the second embodiment concentrates on a second exciter wave, any number of two or more exciter waves can be used to determine the perturbation velocity measurement.

In operation, processor **100** generates two exciter waveforms and communicates the waveforms to the exciter **202** via air tube **107**. The exciter **202** responds by inducing both exciter waveforms into the patient. Noninvasive sensor **210** generates a signal responsive to a hemoparameter and transmits the signal to the processor **100** via wire **109**. As described previously, the exciter may also be an element, such as a loudspeaker, physically attached to the body, in which case the exciter waveforms are sent from the processor to the exciter by means of an electrical connection or wire.

The processor filters the noninvasive sensor signal into components of the natural waveform, a first exciter waveform, a second exciter waveform and noise. The processor determines the phase relationship of the first exciter waveform to a first reference input and determined the phase relationship of the second exciter waveform to a second reference input.

Once the processor has determined the phase of the exciter waveforms, the processor then generates a plurality of points, the slope of which relates to the velocity of the exciter waveform. This is shown in FIG. **8***c*, where the slope of the line is $-2\pi d/Vel$, and where d is distance and Vel is velocity. Since the distance is fixed and the slope is related to blood pressure, and since the slope changes based on changes in blood pressure, the velocity of the exciter waveform is determined.

The technique described above yields a measurement of the group velocity. In contrast, the techniques described in previous embodiments result in the measurement: of a phase

velocity or of a pseudo-phase velocity in the case that the value of n of the phase equation (7) can not be uniquely determined. In a dispersive system these values need not always agree. However, phase, group and pseudo-velocity are monotonically varying functions of pressure. Thus, a measurement of any one of the three is a basis for a pressure prediction, so long as the appropriate pressure-velocity relationship is used. These parameters can be used for the Internal Consistency Analysis trigger described below under the same heading.

An additional benefit of the use of multiple frequency perturbations is that it allows the unique determination of the value of n in the phase measurement equation described above. This allows the use of actual phase velocity, rather than of the pseudo-velocity described earlier in the multi-perturbation analogues of the embodiments depicted in FIGS. **6**, **9** and **10**.

Once the velocity is determined, a prediction of blood pressure is made according to FIG. **8***a*, showing the relationship of velocity to pressure. Thus, it is possible to determine the blood pressure with few, or zero, calibrations.

Another embodiment is depicted in FIG. **11** showing a cross section of an exciter **202** and noninvasive sensor **210** at the same position above the blood vessel **220**. The proximate location of the exciter and the sensor permits measurement of the blood vessel's response to the perturbations. In this embodiment, the noninvasive sensor is responsive to a hemoparameter such as blood flow or blood volume. These parameters can be measured with a sensor such as a photoplethysmograph. Detected changes in the blood vessel due to the natural pulsatile pressure are calibrated using external exciter pressure oscillations and compared against the sensor signal by the processor.

F. Internal Consistency Analysis

Internal Consistency Analysis (ICA) relates to the use of information measured at multiple frequencies to monitor the state of a system, as that state pertains to the behavior of other parameters of the system. The monitoring of the variability or constancy of the state of the system can be used to evaluate the current validity of the expected behavior of the other parameters. The system may be physiological or otherwise. The multiple frequency information may be in the form of discrete or continuous frequency content. The information may be utilized simply, such as in the dependence of a given parameter on frequency, or in more complex ways, such as in the dependence of two non-frequency parameters on each other while taking advantage of the range of parameter space spanned by the data from a range of frequency.

In the embodiment described here, ICA is used in a monitor for determining a physiological parameter of a patient. In such a monitor, ICA is used to determine when the state of the patient has changed in such a way as to make desirable either a recalibration of the monitoring system, or a correction to the measurement to compensate said change of state of the patient. The use of ICA for such purpose is described in detail for the case of monitoring of the blood pressure of a patient. However, the principles of ICA work equally well in monitors of other physiological parameters by the techniques described in this invention.

The physiological state of an artery over the time scale of a blood pressure monitoring period is determined primarily by the level of activity of the smooth muscle component of the artery wall. The level of smooth muscle activity affects both the elastic and viscous properties of the artery wall. The elastic properties of the wall are the main determinants (although viscous properties are involved as well) of the relationship between velocity and pressure (the V-P relationship—see equation 10). This is equally true of relationships between pseudo-velocity or phase and blood pressure. The viscous properties of the wall have a significant influence on a number of observable quantities or relationships, such as the dependence of the propagation velocity on frequency, the propagation attenuation, and others. These observable quantities or relationships can be used to monitor the physiological state of the artery, and hence to monitor the validity of a previous V-P relationship calibration. These observable quantities or relationships may also be used to continuously track, calculate the changes in, and deduce the current V-P relationship.

A number of observable quantities or relationships have been studied in a series of clinical investigations that we have caused to be carried out. Several were found to be well-correlated with the V-P relationship. Two observable quantities called dispersion (D) and attenuation (A) were identified as of particular importance although several other quantities were also viable candidates for use in ICA .

The D quantity, as implemented, was calculated as follows. First calculate the propagation velocities for the frequencies of 300, 400, 500, 600, and 700 Hz as a continuous function of time as the blood pressure pulses. Take the mean of these velocities over a pulse, to produce the velocity at Mean Arterial Pressure (MAP). Take a linear regression of the velocity at MAP vs. frequency using the valid data from all five frequencies. The slope of this line is the dispersion (D). This is an example of a utilization of the multiple frequency information, because the calculated quantity is a relationship between another parameter and frequency.

The attenuation (A) quantity, as implemented, was calculated as follows. First calculate the propagation phase delays for the frequencies of 300, 400, 500, 600, and 700 Hz as a continuous function of time as the blood pressure pulses. Also calculate the propagated amplitude of the exciter waveform (relative to the injected initial amplitude) for the frequencies of 300, 400, 500, 600, and 700 Hz. Calculate the quantity $\ln(Gv^2/\sin(kL/2))$ for each frequency, where G is the relative propagated amplitude, v is the propagation velocity, L is the exciter length, and k is the propagation wave vector. Take a linear regression of $\ln(Gv^2/\sin(kL/2))$ vs. propagation phase using the valid data from all five frequencies. The intercept of this line at a phase of −4 radians is the attenuation (A). This is an example of a more complex utilization of the multiple frequency information, because the calculated quantity is a relationship between two parameters, neither of which represents frequency directly, but the relationship is calculated over a range of parameter space spanned by data from a range of frequency.

There are a number of other observable quantities or relationships and minor modifications on the dispersion (D) and attenuation (A) quantities which may be useful. For example, the described dispersion (D) is calculated at MAP, but it could also be calculated at a different constant blood pressure. Also the described attenuation (A) utilizes an intercept of the regression of $\ln(Gv^2/\sin(kL/2))$ vs. propagation phase, but the slope of this line is another useful quantity.

FIG. **12** is an example flow chart of an embodiment using the above observable quantities or relationships to implement a recalibration triggering technique. The observable quantities or relationships that indicate the state of the system and that can be measured between calibrations, such as the dispersion (D) and attenuation (A) discussed above, are denoted by the term "trigger parameters" (TP). The

parameters describing the behavior of the system that depend on what state the system is in (such as the relationship between velocity and pressure described above), which we are not generally monitoring between calibrations but rather utilizing in the signal processing to produce a calculated output (such as the monitored blood pressure), are denoted by the term "state parameters" SP.

Note that in general each of the terms "trigger parameter" and "state parameter" may indicate parameters of one or more dimensions. For example the dispersion parameter (D) described above, which is a trigger parameter (TP), is one numerical scalar value and is, hence, one dimensional. The combination of D and A is considered a two dimensional trigger parameter. The V-P relationship described above as the primary state parameter is two dimensional if the relationship is modeled as a line, but in general could take on higher or lower dimension. In the discussion that follows the term trigger parameter TP is understood to encompass both the possibility of a single-dimensional and multi-dimensional TP. Likewise, the term state parameter SP is understood to encompass both the possibility of a single-dimensional and multi-dimensional SP. The same concepts can be applied to more complicated quantities using more sophisticated vector, matrix, or tensor mathematics if necessary.

To utilize a TP to deduce a change in SP, we need to know the relationship between TP and SP, for example, how has SP changed if we measure a change in TP. This relationship is denoted with the function F, so that SP2=F(SP1, TP1, TP2). That is to say SP at time **2** is a function of SP at time **1**, TP at time **1**, and TP at time **2**. The function F can generally be quite complicated, or it can be as simple as a linear scaling from the change in TP to the change in SP, for example, (SP2-SP1)=X*(TP2-TP1) where here X is a constant.

The specification of the function F shown as steps **904** and **918** in FIG. **12** can be accomplished in a number of ways. The simplest way to produce an initial F (as in step **904**) is to use a pool of previously collected patient data, containing information on both TP and SP over a range of time and conditions, to develop an approximation of the function. If this initial approximation is found to produce acceptable results in testing, there is no need for step **918**. If testing shows that the initial approximation of F is inadequate, F can be updated for each patient (as in step **918**) using the information obtained by the calibration process. It may be sufficient to rely on calibrations that occur for other reasons to accomplish this updating process, or the device could undergo a series of planned calibrations specifically for this purpose.

At the time of calibration, both initial and subsequent, shown as step **906** in FIG. **12** SP1 is determined from the combination of information from the noninvasive sensor signal and from the calibration device, and TP1 Is determined from the noninvasive sensor signal.

After calibration the device goes on to continuously obtain the noninvasive sensor signal at time **2**, shown as step **908** in FIG. **12**. In the notation of FIG. **12**, time **1** is the time of the last calibration, and time **2** is the subsequent time of continuous, monitoring operation.

Given the continuous noninvasive sensor signal, and the SP1 obtained by the previous calibration, the device can then produce an output blood pressure, as is shown in step **916**.

Given the continuous noninvasive sensor signal, the device can calculate TP2 as is shown in step **910**.

Given TP2, SP1 and TP1 combined with the function F, the device can estimate the current SP2 as is shown in step **912**.

At this point there is an optional variation on the recalibration technique. If it is determined in testing that the estimate of SP2 produced in step **912** is sufficiently accurate, the continuous noninvasive sensor signal and SP2 can be used to produce an output blood pressure, as is shown in step **920**. In this variation step **920** replaces step **916**, which is not performed.

In step **914** the current estimate of SP2 is compared to the SP1 which was calculated at the last calibration. If the change in SP exceeds a predetermined recalibration threshold, the device is instructed to perform a new calibration in step **906**. If the change in SP does not exceed the predetermined recalibration threshold, the device loops back to step **908** to continue acquiring the noninvasive sensor signal and producing blood pressure output. Specification of the recalibration threshold is based on the amount of change in SP that is tolerable before unacceptably inaccurate results are produced. Step **918**, shown in dotted lines, is optional. Step **920**, shown in dotted lines, is an optional replacement for step **916**.

Note that there are many possible ways to implement a recalibration triggering technique, and the simple example shown in FIG. **12** is but one possible methodology. A few possible modifications to the technique include: (a) to decide when to recalibrate based on changes in TP rather than on the changes in SP that are calculated from the changes in TP; (b) to recalibrate based on TP or SP reaching or passing through certain predetermined values rather than changes since the last calibration; or (c) combinations of these and other variations.

The specific detailed embodiment described above is one of several viable trigger techniques using ICA. Other variables that may be used instead of, or in conjunction with, the variables D and or A, include but are not limited to the following: (a) the slope or intercept of a relationship between amplitude (G) and phase of the signal exciter waveform that is expressed in a different functional form than the example used above of $\ln(Gv^2/\sin(kL/2))$ or various comparative measures of such slope or intercept derived using differing frequency combinations; (b) the difference between the phase velocity or group velocity of the signal exciter waveform (or the intercept of the line of best fit to data on a graph of omega versus k, where omega is equal to frequency times two pi); (c) various pulse shape characteristics of either the physiological parameter waveform or the exciter signal velocity waveform such as the ratio of the power in components of frequency greater than 5 Hz to the total power in components of greater than 0.2 Hz (or differences between these two waveforms or between waveforms from different exciter frequencies or different exciters or detectors); (d) heart rate, pulse pressure, pressure, other physiological parameters and ratios thereof; (e) various permutations of the above techniques using metrics derived from more than one detector and or exciter and examining the internal consistency thereof.

The general philosophy of ICA is to use multiple parameters to examine the internal consistency of information derived in different ways from several sources. A further embodiment of ICA involves the use of multiple exciter waveforms as described in section E. Each of these frequencies of perturbation can be used to derive an independent determination of a physiological parameter using the techniques described in this invention. So long as these independent determinations are in reasonable agreement, the system can be allowed to continue to monitor the physiological parameter. If the independent determinations differ by more than some threshold, then a recalibration can be triggered.

In a further embodiment of ICA, the velocity of propagation of the cardiac pulse between two locations on the body is measured using techniques such as are described in U.S. Pat. No. 5,785,659, incorporated herein by reference. This velocity is also related to blood pressure and can be used as an independent predictor of blood pressure once it has been calibrated appropriately. Various changes in this velocity, or differences in the pressure predicted using it and the pressure predicted using the techniques of this invention can be used to trigger a recalibration.

G. Variations on the Disclosed Embodiments

Additional embodiments include an embodiment in which two or more detectors are positioned along the artery at different distances from a single exciter, and an embodiment in which two or more exciters are positioned along the artery at different distances from one or more detectors. In each of these embodiments, the information obtained from each exciter detector pair can be analyzed independently. The multiply redundant measurements of pressure that result can be combined to provide a single pressure determination that may be both more accurate and more immune from noise, motion artifact and other potential error sources. Similar redundancy can be achieved in the embodiments that use multiple exciter waveforms by analyzing the results at each frequency independently and combining the results to provide enhanced robustness.

In addition, any combination of more than two elements (e.g. two exciters and one detector, two detectors and one exciter, one exciter and three detectors) allows the value of n in the phase equation (7) to be uniquely determined so long as the spacing of two of the elements is sufficiently small to be less than a wavelength of the propagating perturbation. Since the possible range of perturbation wavelengths at a given-pressure can be determined from a pool of patients, selection of the appropriate spacing is straightforward and can be incorporated into the geometrical design of the device.

H. Conclusion

A close relationship between physiological parameters and hemoparameters supplies valuable information used in the present invention. The perturbation of body tissue and sensing the perturbation also supplies valuable information used in the present invention. Although the preferred embodiment concentrates on blood pressure, the present invention can also be used to analyze and track other physiological parameters such as vascular wall compliance, changes in the strength of ventricular contractions, changes in vascular resistance, changes in fluid volume, changes in cardiac output, myocardial contractility and other related parameters.

Calibration signals for the present invention can be obtained from a variety of sources including a catheter, manual determination, or other similar method.

The DC offset for the physiological parameter waveform can be obtained in a variety of ways for use with the present invention.

The exciter of the preferred embodiment uses air, but any suitable fluid or solid can be used. Moreover, various exciter techniques can be used for inducing an exciter waveform into the patient such as an acoustic exciter, an electromagnetic exciter and an electromechanical exciter (e.g. piezoelectric device).

Various noninvasive sensors have been developed for sensing hemoparameters. These sensor types include piezoelectric, piezoresistive, microphones, impedance plethysmograph, photoplethysmograph, various types of strain gages, air cuffs, tonometry, conductivity, resistivity and other devices. The present invention can use any sensor that provides a waveform related to the hemoparameter of interest.

Having disclosed exemplary embodiments and the best mode, modifications and variations may be made to the disclosed embodiments while remaining within the subject and spirit of the invention as defined by the following claims.

What is claimed is:

1. A noninvasive blood pressure monitor, comprising:

an input calibration signal from a calibration device configured to provide an accurate representation of the blood pressure of a patient;

an input noninvasive sensor signal from a sensor configured to detect one or more attributes of a perturbation of an artery of the patient; and

a processor which determines when to employ the input calibration signal to recalibrate one or more of a plurality of parameters, wherein the processor uses the plurality of parameters and the input noninvasive sensor signal to continuously calculate the blood pressure of the patient,

wherein the one or more parameters comprise a combination of values of a pressure-volume relationship and a trigger parameter.

2. The noninvasive blood pressure monitor of claim 1, wherein the trigger parameter comprises a dispersion parameter.

3. The noninvasive blood pressure monitor of claim 1, wherein the trigger parameter comprises an attenuation parameter.

4. A monitor for determining a physiological parameter of a patient comprising:

a calibration device configured to provide a calibration signal representative of one of a patient's physiological parameters;

an exciter adapted to be positioned over a blood vessel of the patient and configured to induce a transmitted exciter waveform into the patient;

a noninvasive sensor adapted to be positioned over said blood vessel and configured to sense a hemoparameter and to generate a noninvasive sensor signal representative of said hemoparameter containing a component of a received exciter waveform;

a processor configured to determine a relationship between a property of said received exciter waveform and a property of said physiological parameter;

wherein said processor includes a filter configured to separate a signal exciter waveform component of said received exciter waveform from at least one other component of said received exciter waveform;

wherein said processor is connected to receive said calibration signal and said noninvasive sensor signal and is configured to determine said physiological parameter based at least in part on said calibration signal, said signal exciter waveform component, and said relationship;

wherein said processor is configured to determine the validity of said calibration signal and to initiate a calibration when said calibration signal is not valid;

wherein said processor employs an Internal Consistency Analysis (ICA) technique to determine when said calibration signal is not valid; and

wherein said ICA technique includes determining a plurality of parameters and comparing the parameters over

time to a predetermined threshold to determine when said calibration signal is not valid.

5. A monitor for determining a physiological parameter of a patient comprising:

a calibration device configured to provide a calibration signal representative of one of a patient's physiological parameters;

an exciter adapted to be positioned over a blood vessel of the patient and configured to induce a vibrational transmitted exciter waveform into the patient;

a noninvasive sensor adapted to be positioned over said blood vessel and configured to sense a hemoparameter and to generate a noninvasive sensor signal representative of said hemoparameter containing a component of a received exciter waveform;

a processor configured to determine a relationship between a property of said received exciter waveform and a property of said physiological parameter;

wherein said processor includes a filter configured to separate a component of said noninvasive sensor signal having a phase that varies with blood pressure from at least one other component of said noninvasive sensor signal having a phase that does not so vary;

wherein said processor is connected to receive said calibration signal and said noninvasive sensor signal and is configured to determine said physiological parameter based at least in part on said calibration signal, said component having a phase that varies with blood pressure, and said relationship;

wherein said processor is configured to determine the validity of said calibration signal and to initiate a calibration when said calibration signal is not valid;

wherein said processor employs an Internal Consistency Analysis (ICA) technique to determine when said calibration signal is not valid; and

wherein said ICA technique includes determining a plurality of parameters and comparing the parameters over time to a predetermined threshold to determine when said calibration signal is not valid.

6. A monitor for determining a physiological parameter of a patient, comprising:

a calibration device configured to provide a calibration signal representative of one of a patient's physiological parameters;

at least one exciter adapted to be positioned over a blood vessel of the patient and configured to induce a plurality of different frequency transmitted exciter waveforms into the patient;

a noninvasive sensor adapted to be positioned over said blood vessel and configured to sense a hemoparameter and to generate a noninvasive sensor signal representative of said hemoparameter containing components of a plurality of different frequency received exciter waveforms;

a processor configured to determine a relationship between a property of one of said received exciter waveforms and a property of said physiological parameter;

wherein said processor is connected to receive said calibration signal and said noninvasive sensor signal and is configured to determine said physiological parameter based at least in part on said calibration signal, said noninvasive sensor signal and said relationship;

wherein said processor is configured to determine the validity of said calibration signal and to initiate a calibration when said calibration signal is not valid;

wherein said processor employs an Internal Consistency Analysis (ICA) technique to determine when said calibration signal is not valid; and

wherein said ICA technique includes determining a plurality of parameters and comparing the parameters over time to a predetermined threshold to determine when said calibration signal is not valid.

7. A method for determining a physiological parameter of a patient comprising:

providing a calibration signal representative of one of a patient's physiological parameters and storing the calibration signal;

inducing a transmitted exciter waveform into the patient;

noninvasively sensing a hemoparameter and generating a noninvasive sensor signal representative of said hemoparameter containing a component of a received exciter waveform; and

processing said noninvasive sensor signal including the steps of:

(a) determining a relationship between a property of said received exciter waveform and a property of said physiological parameter;

(b) separating a signal exciter waveform component of said received exciter waveform, from at least one other component of said received exciter waveform;

(c) determining said physiological parameter based at least in part on said calibration signal, said signal exciter waveform component, and said relationship;

wherein processing said noninvasive sensor signal also includes the step of determining the validity of said calibration signal and initiating said step of providing a calibration signal when said calibration signal is not valid;

wherein said processing includes employing an Internal Consistency Analysis (ICA) technique to determine when said calibration signal is not valid; and

wherein said ICA technique includes determining a plurality of parameters and comparing the parameters over time to a predetermined threshold to determine when said calibration signal is not valid.

8. A method for determining a physiological parameter of a patient comprising:

providing a calibration signal representative of one of a patient's physiological parameters and storing the calibration signal;

inducing a vibrational transmitted exciter waveform into the patient;

noninvasively sensing a hemoparameter and generating a noninvasive sensor signal representative of said hemoparameter containing a component of a received exciter waveform; and

processing said noninvasive sensor signal including the steps of:

(a) determining a relationship between a property of said received exciter waveform and a property of said physiological parameter;

(b) separating a signal exciter waveform component of said noninvasive sensor signal having a phase that varies with blood pressure, from at least one other component of said noninvasive sensor signal having a phase that does not so vary;

(c) determining said physiological parameter based at least in part on said calibration signal, said component having a phase that varies with blood pressure, and said relationship;

wherein processing said noninvasive sensor signal also includes the step of determining the validity of said calibration signal and initiating said step of providing a calibration signal when said calibration signal is not valid;

wherein said processing includes employing an Internal Consistency Analysis (ICA) technique to determine when said calibration signal is not valid; and

wherein said ICA technique includes determining a plurality of parameters and comparing the parameters over time to a predetermined threshold to determine when said calibration signal is not valid.

9. A method of determining a physiological parameter of a patient, comprising the steps of:

providing a calibration signal representative of one of a patient's physiological parameters and storing the calibration signal;

inducing a plurality of different frequency transmitted exciter waveforms into the patient;

noninvasively sensing a hemoparameter and generating a noninvasive sensor signal representative of said hemoparameter containing components of a plurality of different frequency received exciter waveforms;

processing said noninvasive sensor signal including the steps of:

(a) determining a relationship between a property of one of said received exciter waveforms and a property of said physiological parameter;

(b) determining said physiological parameter based at least in part on said calibration signal, said noninvasive sensor signal and said relationship;

wherein processing said noninvasive sensor signal also includes the step of determining the validity of said calibration signal and initiating said step of providing a calibration signal when said calibration signal is not valid;

wherein said processing includes employing an Internal Consistency Analysis (ICA) technique to determine when said calibration signal is not valid; and

wherein said ICA technique includes determining a plurality of parameters and comparing the parameters over time to a predetermined threshold to determine when said calibration signal is not valid.

* * * * *